

EPA Jacket 88450-1

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 2-12-15

Experts In-Processing Signature: B.D. Date 2-20-15 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date

EPA Reg. Number: <u>88450-R</u>		EPA Receipt Date: <u>2-12-15</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

Documentation: Pass

Required forms are complete

Inerts: Pass

Approved for non-food use

II-3: Pass

MRID 495657 (eSub)

Status: Pass

KC 02/27/2015

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 19, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-500099
EPA File Symbol or Registration Number: 88450-R
Product Name: LuminOre CopperTouch Antimicrobial Surfaces
EPA Receipt Date: 12-Feb-2015
EPA Company Number: 88450
Company Name: LUMINORE, INCORPORATED

ELIOT HARRISON
LEWIS & HARRISON
LUMINORE, INCORPORATED
122 C ST., NW, SUITE 505
WASHINGTON, DC 20001

SUBJECT: Receipt of Application and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A540

NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. We will also initiate a refund of your \$1,216 overpayment after processing of this action has been completed. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-0228.

Sincerely,

Neressa Owens
Front End Processing Staff

Information Technology & Resources Management Division

Fee for Service

TD
{964333"~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☒ Fee Waiver?

☐ volpay % Reduction: 75

for Division

- ☒ AD
- ☐ BPPD
- ☐ RD

Risk Mgr. 33

Receipt No.

S- 964333

EPA File Symbol/Reg. No.

88450-R

Pin-Punch Date:

2/12/2015

☐ This item is NOT subject to FFS action.

Action Code:

Requested: ~~4863~~ A540

Granted: ~~2931.52~~ A540

Amount Due: \$ ~~2477.52~~ 4863

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: T. L. Brown

Date: 2-18-15

Remarks:

e-Submission

A540 - New end use product.

- Must submit or reference Group A and B product chemistry, toxicity, and/or efficacy data for each proposed product.
- Data waivers may be requested. Chemistry data on the TGAI in addition to the EP is required if an unregistered source is used.

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.1550	Product Identity & Composition	/		
830.1600	Description of materials used to produce the product	/		
830.1650	Description of formulation process	/		
830.1670	Discussion on the formation of impurities	/		
830.1700	Preliminary analysis	/		
830.1750	Certified limits (158.345)	/		
830.1800	Enforcement analytical method	/		

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.6302	Color	/		
830.6303	Physical State	/		
830.6304	Odor	/		
830.6313	Stability to normal and elevated temperatures metal and metal ions			
830.6314	Oxidation/Reduction (Chemical incompatibility)	/		
830.6315	Flammability	/		
830.6316	Explosibility	/		
830.6317	Storage stability*	/		
830.6319	Miscibility	/		
830.6320	Corrosion Characteristics*	/		
830.6321	Dielectric Breakdown Voltage	/		
830.7000	pH	/		
830.7050	UV/ Visible Absorption			
830.7100	Viscosity	/		
830.7200	Melting Point			
830.7220	Boiling Point			
830.7300	Density	/		
830.7370	Dissociation Constant			
830.7550	Partition Coefficient			
830.7840	Water Solubility			
830.7950	Vapor Pressure			

Grayed out = data not required

*May not be included with initial application

A540 – Acute Toxicity Requirements

New products must either:

- 1) supply the product specific acute toxicity 6 pack data (listed below),
- 2) provide a bridging rationale document or waiver request or,
- 3) use the cite all method of data compensation, if applicable. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cite All	Selective	Waiver Request	Bridging Rational
830.1100	Acute Oral (LD50)		✓		
830.1200	Acute Dermal (LD50)		✓		
830.1300	Acute Inhalation (LC50)		✓		
830.2400	Acute Eye Irritation		✓		
830.2500	Acute Dermal Irritation		✓		
830.2600	Dermal Sensitization		✓		

Receipt for Section 3									
S: 964333	Milestone Email: <input type="text"/>								
Regulatory Type: Product Registration - Section 3	Resubmission: <input type="radio"/> Yes <input checked="" type="radio"/> No		<input type="button" value="Print Letter"/> <input type="button" value="Enter More Information"/> <input type="button" value="Tracking"/>						
Application Type: New Registration	Fee For Service: <input checked="" type="radio"/> Yes <input type="radio"/> No								
Company: 88450 LUMINORE INCORPORATED	Billable: <input checked="" type="radio"/> Yes <input type="radio"/> No								
Risk Manager: Antimicrobials Division Risk Management Team 33	V								
Product #: 88450-R	Product Name: LuminOre Copper Touch Antimicrobial Surface								
Override#									
Me Too Section 3	Me Too Product Name								
Application Date: 10-Feb-2015	OPP Rec'd Date: 12-Feb-2015	<table border="1"> <thead> <tr> <th colspan="2">Receipt Content</th> </tr> </thead> <tbody> <tr> <td>Study</td> <td></td> </tr> <tr> <td>CSF</td> <td></td> </tr> </tbody> </table>		Receipt Content		Study		CSF	
Receipt Content									
Study									
CSF									
Front End Date: 13-Feb-2015	Risk Manager Send Date:								
FFS Due Date:	Negotiated Due Date:								
OPP Target Date:									
Fast Track: <input type="checkbox"/>	New Ingredient: <input type="checkbox"/>	<input type="button" value="View/Edit"/>							
Receipt Description: Associated with e-Submission pkg 7265. Application for registration <input type="text"/>									
Form A: <input type="checkbox"/>	Signature Date: <input type="text"/>	Form B: <input type="checkbox"/>	Signature Date: <input type="text"/>						

e-Submission

LuminOre, Inc.
6060 Corte del Cedro
Carlsbad, CA 92011
(760) 431-7705

CHASE
JPMorgan Chase Bank, N.A.
www.Chase.com
90-7162/3222

22607

2/3/2015

PAY TO THE ORDER OF Environmental Protection Agency \$ ****2,431.50**
Two Thousand Four Hundred Thirty-One and 50/100***** DOLLARS

Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Thomas J. Valent
AUTHORIZED SIGNATURE

MEMO

⑈022607⑈

LuminOre, Inc.

22607

Environmental Protection Agency
Professional Services:Legal Expense

2/3/2015
Registration Fees: (2) LuminOre Copper & LuminOr

2,431.50

Chase Checking (102

2,431.50

e-Submission

 EPA United States Environmental Protection Agency Washington, DC 20460	<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other:	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 88450-	2. EPA Product Manager Seiichi Murasaki	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) LuminOre CopperTouch Antimicrobial Surfaces	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Luminore Inc. 6060 Corte del Cedro Carlsbad, CA 92011		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

PLEASE SEND ALL CORRESPONDENCE TO "CONTACT POINT" LISTED BELOW

☐ Check if this is a new address

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below

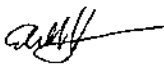
Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Registration application for new end-use product. PRIA Category is A540; (New end-use product, 2mm Uses Only).
Registrant is requesting fee waiver (75%).

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
*Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 1 lb - bulk	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Eliot Harrison, Lewis & Harrison, 122 C St. NW, Suite 505, Washington, DC 20001	Title Agent for LuminOre Inc.	Telephone No. (Include Area Code) 202-393-3903 x 14
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped) 
2. Signature	3. Title Agent for LuminOre CopperTouch	
4. Typed Name Eliot Harrison, Lewis & Harrison	5. Date February 10, 2015	

PRIA Assessment Form

Reg. No.	PRIA Code	Due Date	45/90 Date	Product Name
88450-R	AS40	8/6/15	4/20/15	
Ingredient Statement	Label	CSF	FES	MOS
851. Copper	✓	✓	NO	selective
Application Form	Data Matrices	Fee Paid	Inerts Cleared?	
✓	✓	✓	Yes for NF	

Description

Submission Description	① chem data ② acetox water ③ efficacy	copper touch antimicrobial surfaces submit to 82012-1
Data Submitted		
Deficiencies	—	

Uses: Fill in Registration Number of other registered pesticides for each a.i. and rate.

If using EPA registered source, does label support the proposed uses?	
Reg. No(s)	

	Uses					
AI & Rate						

To-Do List and Timeline

Follow Up	Timeline
Complete for me too	
talk to Karen	

DECISION PKG. 500099
SUBMISSION BAR CODE # 964335

SUBM US DATE 08/06/15
REVIEWER (K)

~~CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS~~

FILE SYMBOL/REG NO. 88450-1 PM 35 ACTION CODE 1510

DESCRIPTOR FQPA NFQPA

[] CHILD RESISTANT PACKAGING: [] REQUIRED [] NOT REQUIRED
REGISTRATION TYPE: [] CONDITIONAL [] UNCONDITIONAL [] RESTRICTED USE

DATE ON APPLICATION 02/10/15 EPA RECEIVE DATE 02/12/15 PM RECEIVE DATE 02/19/15

METHOD OF SUPPORT FORMULATORS EXEMPTION
[] GITE-ALL [] SELECTIVE [] SUBMITTED [] NOT SUBMITTED
[] NOT SUBMITTED [] N/A [] N/A

REVIEW(S) REQUESTED	DATA PAGE #	DATE SENT	DUE DATE	DATE RETURNED
CHEMISTRY				
EFFICACY				
ACUTE TOX				
RASSB TOX				
ENVIRON. FATE				
FISH/WILDLIFE				
OTHER:				

STATUS

RESPONSE CODE 1800 RESPONSE DATE 08/05/15

SCIENCE GROUP	DIVISION	BRANCH	SECTION	CSF Y/N	LABEL Y/N
CHEMISTRY	AD	EASSB	CTT		
EFFICACY	AD	EASSB	EET		

PROCESSING REQUEST

Reg # 88450-1

Decision #500099

Description: Registration Notice

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☒ Dated:

08/05/2015

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 07/29/15

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Karen M. Leavy

Division: AD

PROCESSING REQUEST

Phone: 308-6237

Date: 08/06/2015



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

88450-1

Date of Issuance:

8/5/15

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

LuminOre Copper Touch
Antimicrobial Surfaces

Name and Address of Registrant (include ZIP Code):

LuminOre Inc.
6060 Corte del Cedro
Carlsbad, CA 92011

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Julie Chao, Product Manager 33
Regulatory Management Branch 1, Antimicrobials Division (7510P)

Date:

8/5/15

2. You are required to comply with the data requirements described in the DCI or EDSP Order identified below:

- a. Copper GDCI-022501-1258

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

3. Comply with the following, additional terms of registration:

Term 1

LuminOre will prepare and implement a LuminOre Copper Touch Antimicrobial Surfaces Stewardship Plan (“the Plan”) designed to support the responsible use of antimicrobial copper products. The Plan will be submitted for EPA review and approval within two months after the registration date. If EPA determines at any time after 18 months following registration that the Plan is not being adequately or timely implemented or that implementation of the Plan is not effectively ensuring the proper sale, distribution, or use of antimicrobial copper products, the registration may be automatically cancelled by the Agency by order with no opportunity for a hearing but only after notification to the Registrant and an opportunity to meet with the Director of the Office of Pesticide Programs.

The Plan will include, at a minimum, the following elements:

- (a) Outreach to the infection control community, including:
 - (i) A goal of educating and reinforcing, for infection control professionals and other product users, the proper use of LuminOre Copper Touch Antimicrobial Surfaces.
 - (ii) Written (including electronic) communications directed to associations of infection control professionals, including at the least APIC, ASHES, and any other relevant organizations identified by CDA or EPA, and State Departments of Health.
 - (iii) Outreach communications will be sent within six months after the date of registration and within one year after the date of registration, and then annually thereafter on the anniversary of the date of the registration unless more frequent outreach is deemed necessary.
 - (iv) The content of the outreach communications will include statements explaining the registered claims and applications of LuminOre Copper Touch Antimicrobial Surfaces, as well as their proper use. The communications also will inform the recipients about (1) the LuminOre Copper Touch Antimicrobial Surfaces WorkGroup (see below) and invite their participation; (2) other sources of information on LuminOre Copper Touch Antimicrobial Surfaces, including the Stewardship Website (see below). Additional content of outreach efforts will be developed as part of the Working Group activities.
- (b) Development of a Stewardship Website (“the Website”) under the auspices of the LuminOre Incorporated.

- (i) The Website will serve as a resource for conveying accurate information to the public about the efficacy and proper use of LuminOre Copper Touch Antimicrobial Surfaces.
 - (ii) The Website will include information on proper labeling and claims (including advertising); supporting science; applications; maintenance; and federal and state regulations and statutory requirements.
 - (iii) A question and answer or Frequently Asked Questions (FAQs) section will be incorporated to address common issues or questions raised with regard to LuminOre Copper Touch Antimicrobial Surfaces.
 - (v) Links will be arranged and established by LuminOre between the Stewardship Website and the websites of appropriate infection control organizations, including but not limited to APIC and ASHES.
- (c) Establishment of a LuminOre Copper Touch Antimicrobial Surfaces Working Group (“the Working Group”).
- (i) Invited participants will include component makers, and representatives from the infection control community, including appropriate trade associations (e.g., APIC and ASHES) and State Departments of Health.
 - (ii) The Working Group will meet at least twice a year, either in person or by live video conferencing (WEBEX) or teleconferencing.
 - (iii) The Working Group will serve as a forum to expand educational efforts, develop outreach communications, and address any questions or concerns from the public and infection control community.
 - (iv) LuminOre shall provide EPA with minutes of any such meetings within 60 days of the end of any such meeting.

Term 2

For at least the first 24 months after registration or until the Agency terminates this condition, whichever is later, LuminOre will submit to EPA sample advertising materials. Advertising materials will be representative of advertisements intended for use in the marketplace.

4. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those

claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 07/29/2015

If you have any questions, please contact Karen M. Leavy by phone at (703)-308-6237, or via email at Leavy.Karen@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Julie Chao".

Julie Chao, Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure

Master Label Containing

Sublabel 1. Complete Label

Sublabel 2. Hang Tag Label

Sublabel 1. Complete Label

LuminOre Copper Touch Antimicrobial Surfaces
Antimicrobial Copper
Surface Active Product

ACTIVE INGREDIENT:

Copper*85.0%

OTHER INGREDIENTS:15.0%

TOTAL100.00%

*Contain 3.8 oz. of copper per ft²

EPA Reg. No.: 88450-1

EPA Est. No.: XXXXX-XX-XXX

Net Wt.: XX

LuminOre, Incorporated
6060 Corte del Cedro
Carlsbad, CA 92011

ACCEPTED

Aug 05, 2015

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 88450-1

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

(Note: The surface of this product contains copper, which functions as an antimicrobial agent. Product types that can be sold pursuant to this label are listed below. None of these product types are approved for direct food contact or food packaging uses).

Touch Surface Components

Healthcare Facilities

- Bedrails, footboards
- Toilet seats
- Flush handles
- Over-bed tables
- Bed-side tables in hospitals, extended care facilities, senior housing etc. (knobs, pulls, handles; surfaces)
- Handrails, (corridor/hallways) (Senior housing), automatic door push plates
- Stair rails, handrails, tubular railing, and supports, rail fittings T's, elbows and brackets
- Bedrails, assistance rails,
- Toilet safety rails
- Carts
 - Hospital carts (table surfaces, handles, legs)
 - Computer carts
 - Record carts
 - Phlebotomy carts
 - Other Carts (tables/surfaces, shelving, railings, handles, pulls)
- Equipment carts (horizontal surfaces, frames, handles)
- Door push plates, kick plates, mop plates, stretcher plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Alcohol sanitizer dispenser, handle
- Paper towel holders, facial tissue holders, toilet paper holders
- Air hand dryer, controls and push buttons on air hand dryers
- Hydrotherapy tanks (whirlpool tanks): shells, covers, headrests, drain fittings (outer surfaces without water contact)
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Panic bars on emergency room doors
- Towel bars
- Countertops and tabletops (non-food use only)
- Door pulls,
- Toilet and urinal hardware, levers, push buttons
- Closures
- Vertical locking arms
- Vertical cover guards
- Protection bars
- Light switches, switch plates
- Visitor chairs: armrests, metal frames

- Telephone handsets and surfaces (housings), keypad
- Kitchen surfaces (non-food contact only): table tops, cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Floor tiles
- Wall tiles
- Instrument handles
 - Medical equipment knobs, pulls and handles for:
 - Drug delivery systems
 - Monitoring systems
 - Hospital beds
 - Office equipment
 - Operating room equipment
 - Stands and fixtures
 - Types of knobs: e.g., Prong, fluted, push/pull, T-handle, tapered, and ball knobs
- Intravenous (IV) poles, bases, hangers, clips
- Trays (instruments, non-food contact)
- Pans (bed)
- Walkers, wheelchair handles, and tubular components
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise and rehabilitation equipment, handles, bars
- Physical therapy equipment: physical therapy tables, treatment chairs and portable taping tables
- Chairs (shower chairs, patient chairs, visitor chairs): rails, backs, legs, seats
- Lighting products: X-ray illuminators, operating rooms, patient examination rooms, surgical suites, and reading lamps for hospital rooms and assisted living facilities etc. Components can include bases, arms, housings, handles, hinges)
- Headwall systems: the unit themselves, outlet covers, knobs and dials, lighting units (lamp housings and adjustable arms), CRT monitors with rotating knobs and levers and adjustments. Baskets, monitor housings, knobs, baskets, tables, IV poles
- Critical care cart: Table top, drawer, drawer pull,
- Bedside lavatory: sink, faucet, handles, drawer pulls, toilet seat, toilet seat cover, toilet handle, door and cabinet facings, counter tops
- Grab handles on privacy curtains
- Lids of laundry hampers, trash canisters, and other containers
- Electrical wallplates

Community Facilities (including various public and commercial buildings)

- Shopping cart handles, child seats, handrails
- Toilet seats
- Flush handles
- Gym/Health club lockers, locker handles, locker shelving, trainers' tables,
- Ice and water dispensers (outer surfaces without water contact)
- Elevator: handrail, control panel, buttons, interior walls, floor tiles, exterior call button plate
- Paper towel dispensers. Housing itself, (turn) handle, (push) handle
- Soap holder
- Soap dispenser (wall mounted): push bar and dispenser itself
- Soap dispenser (sitting on counter): dispenser housing itself, push mechanism
- Toilet paper dispenser (housing)
- Light switches, switch plates

- Lids of laundry hampers, trash canisters, and other containers
- Magazine rack
- Signage
- Vending machines (non-food contact only)
- Window sills
- Electrical wallplates

Residential Buildings (including homes, apartments, apartment buildings and other residences)

- Kitchen surfaces (non-food contact only): table tops, handles, cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Toilet seats
- Flush handles
- Bedrails, footboards
- Handrails
- Stair rails
- Door push plates
- Sinks: spigots, drains, sinks themselves
- Faucet: handles, spigot, drain control lever
- Paper towel holders, facial tissue holders, toilet paper holders
- Door handles, doorknobs (outer touch surfaces)
- Grab bars in bathrooms showers and bathtubs
- Towel bars
- Countertops and tabletops (non-food use only)
- Door pulls
- Toilet and urinal hardware, levers, push buttons
- Toilet seat inlay for lifting of seat
- Light switches, switch plates
- Telephone handsets and surfaces (housings), keypad
- Floor tiles
- Wall tiles
- Computer keyboards: keys, housings, computer mouse surfaces
- Exercise equipment, handles, bars
- Window treatments (cord pulls), Venetian blinds (wands, cord pulls)
- Television control knobs and buttons
- Lids of laundry hampers, trash canisters, and other containers
- Television remote
- Magazine rack
- Radiator cover
- Window sills
- Electrical wallplates
- Baby cribs: rails, fittings, brackets, supports
- Bowl stands
- Monitor (television, computer, etc.) housing

Mass Transit Facilities

- Handrails

- Stair rails, tubular railing, and supports; elbows and brackets
- Door push plates, kick plates
- Door handles, door knobs (outer touch surfaces)
- Grab bars and handles
- Tiles: wall, floor
- Chairs and benches: rails, backs, legs, seats
- Window sills, pulls, and handles
- Signage
- Vending machines (non-food contact only)

Other

- Play area equipment (indoor only): bars, handles, chains, push plates, handrails, stair rails and risers, wheels, knobs, flooring
- Chapel pews

STORAGE AND DISPOSAL

Dispose of by recycling or put in trash.

WARRANTY STATEMENT

If used as intended, this product is wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.

Sublabel 2. Hang Tag Label

(Note: The product types listed above may be sold and distributed under EPA Registration Number 88450-X. These products must bear the label below, with one or more of the listed claims.

FRONT PANEL

LuminOre Copper Touch Antimicrobial Surfaces

Active Ingredient:

Copper* 85.0%

Other..... 15.0%

[Total 100.0%]

See [Back/Side Panel][Insert] for Directions
for Use

NET WEIGHT: lbs [brand name]

*Contains 3.8 oz. of copper per ft²

BACK/INSERT PANEL

LuminOre Copper Touch Antimicrobial Surfaces

Laboratory testing has shown that when cleaned regularly this surface:

- Continuously reduces bacterial* contamination, achieving 99.9% reduction within 2 hours of exposure.
- Kills greater than 99.9% of Gram-negative and Gram-positive bacteria* within 2 hours of exposure.
- Delivers continuous and ongoing antibacterial* action, remaining effective in killing greater than 99.9% of bacteria* within 2 hours.
- Kills greater than 99.9% of bacteria* within 2 hours and continues to kill 99% of bacteria* even after repeated contaminations.
- Helps inhibit the buildup and growth of bacteria* within 2 hours of exposure between routine cleaning and sanitizing steps.
- This product continuously kills bacteria left behind [by dirty hands][on the surface] killing more than 99.9% of bacteria within 2 hours.

* *Staphylococcus aureus*, *Enterobacter aerogenes*, *Methicillin-Resistant Staphylococcus aureus (MRSA)*, *Escherichia coli* 0157:H7 and *Pseudomonas aeruginosa*

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Proper Care and Use. (The following paragraph should appear on items intended to be used in health care facilities) Clean and sanitize according to standard practice. Healthcare facilities must maintain the product in accordance with infection control guidelines. The use of this surface is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces. This surface has been shown to reduce microbial contamination, but does not necessarily prevent cross contamination.

This surface may be subject to recontamination and the level of active bacteria at any time will depend on the frequency and timing of recontamination and cleanliness of the surface (among other factors). In order to have proper antimicrobial effect, this product must be cleaned and maintained according to the directions for use.

Do not wax, paint, lacquer, varnish, or otherwise coat this product.

Routine cleaning to remove dirt and filth is necessary for good sanitation and to assure the effective antibacterial performance of this surface. Cleaning agents typically used for traditional hard, non-porous touch surfaces are permissible. The appropriate cleaning agent depends on the type of soiling and the measure of sanitization required. Normal tarnishing or wear of this surface will not impair antibacterial effectiveness.

Not approved for direct food contact or food packaging uses.

[Items exposed to outdoor environmental conditions are not representative of indoor laboratory test conditions, and, therefore, may impart reduced efficacy if not cleaned when visibly soiled.]

STORAGE AND DISPOSAL

Dispose of by recycling or put in trash.

WARRANTY STATEMENT

If used as intended, this product is wear-resistant and the durable antibacterial properties will remain effective for as long as the product remains in place and is used as directed.

EPA Reg. No. 88450-1

EPA Est. No. XXXX-

Manufactured by:

LuminOre, Incorporated, 6060 Corte del Cedro, Carlsbad, CA 92011

Eliot Harrison

From: Perry, Mark <Perry.Mark@epa.gov>
Sent: Monday, June 30, 2014 12:03 PM
To: Eliot Harrison
Subject: RE: Luminore Copper Touch

Eliot,

This material is fine to use.

Mark P.

From: Eliot Harrison [mailto:eharrison@lewisharrison.com]
Sent: Monday, June 30, 2014 10:38 AM
To: Perry, Mark
Subject: RE: Luminore Copper Touch

Hi Mark,
The specifications for the aluminum-magnesium substrate are:

93.9% - Aluminum
5.1% - Magnesium
0.8% - Manganese
0.12% - Chromium

Any issues with the manganese and chromium impurities in the substrate?

Thanks,
Eliot

From: Perry, Mark [mailto:Perry.Mark@epa.gov]
Sent: Thursday, May 29, 2014 11:34 AM
To: Eliot Harrison
Cc: Hebert, John
Subject: RE: Luminore Copper Touch

Eliot,

Yes, this testing will support claims for all three substrates identified below. However, as part of the submission you should include information to support that the product adheres to all metals, composites and wood types that you want to include on the label. Some metals are flexible, some wood types are very soft and/or porous, and some composites may be very flexible and/or porous... these will be issues that need to be addressed. Further, the label will need language that specifies the physical condition and location of the substrate(s) to be treated.

Mark

From: Eliot Harrison [mailto:eharrison@lewisharrison.com]
Sent: Thursday, May 29, 2014 9:59 AM
To: Perry, Mark

e-Submission

Cc: Hebert, John
Subject: RE: Luminore Copper Touch

Hi Mark,

Thanks. Just to confirm, Luminore will run the studies using aluminum-magnesium (5% magnesium) as the only substrate and assuming the results are reviewed by the Agency as passing this will allow Luminore Copper Touch to be applied to the following substrates: metal, composite, wood.

Best regards,
Eliot

From: Perry, Mark [<mailto:Perry.Mark@epa.gov>]
Sent: Friday, May 23, 2014 9:45 AM
To: Eliot Harrison
Cc: Hebert, John
Subject: RE: Luminore Copper Touch

Eliot,

We will go with what Tajah agreed to but I would rather have all three lots performed with an aluminum-magnesium (5% magnesium) alloy as the only substrate. Additional orgs can be two lots per, with the this same substrate.

Mark

From: Eliot Harrison [<mailto:eharrison@lewisharrison.com>]
Sent: Thursday, May 22, 2014 7:16 PM
To: Perry, Mark
Cc: Hebert, John
Subject: RE: Luminore Copper Touch

Hi Mark,

Regarding point 2, we did discuss this issue with Tajah and we thought she agreed to what I described (see attachment). Do you think there are any bridging or other types of studies that could be done to reduce full testing for each substrate? The cost per test is approximately 65K for two organisms and 140K for five organisms (matching what is currently approved for CDA and Cupron). So, if we have to test 4 substrates that will be 250K-640K.

Thanks,
Eliot

From: Perry, Mark [<mailto:Perry.Mark@epa.gov>]
Sent: Wednesday, May 21, 2014 1:50 PM
To: Eliot Harrison
Cc: Hebert, John
Subject: RE: Luminore Copper Touch

Hi Elliot,

Points 1 and 3 below are correct, but what you describe in point 2 is not adequate. Three lots of test material should be tested against 2 metal, 1 composite and 1 wood substrate (3 lots per substrate, per protocol). The metal substrates selected should be known to react with (or displace) copper... I would recommend using iron as one substrate. Although

these protocols have not been used with substrate materials, we think this approach is similar to what has been required previously.

Let me know if you have more questions,

Mark

From: Eliot Harrison [<mailto:eharrison@lewisharrison.com>]

Sent: Tuesday, May 20, 2014 2:50 PM

To: Perry, Mark

Cc: Hebert, John

Subject: Luminore Copper Touch

Hi Mark,

As a follow-up to our meeting on May 1st and my discussion with John Hebert last week, I am writing you to request Agency concurrence with Luminore's efficacy testing plans for Luminore Copper Touch (copper coated substrates).

- 1) To support the continuous bactericidal activity claim, Luminore will use the same protocols that were used to satisfy the efficacy data requirement for the copper alloys. These protocols are: (a) Test Method for Determining Efficacy of Antimicrobial Surfaces as Sanitizers; (b) Residual Self-Sanitizing Activity of Treated Surfaces (with exposure and wear); and (c) Continuous Reduction of Bacterial Contamination on Treated Surfaces. Luminore recognizes that additional studies may need be to be conducted once the Agency's issues updated protocols for surface active products.
- 2) For each protocol, 3 lots of product will be tested per organism (*S. aureus* and *E. aerogenes*). The lots will be distinguished by substrate. Accordingly, one lot will be a metal substrate coated with copper; the second lot will be a composite substrate coated with copper and the third lot will be a wood substrate coated with copper.
- 3) Each lot will be tested at the lower certified level for copper. Accordingly, there is no requirement for an aged sample.

Please let me know if the Agency concurs with the above or if any changes are necessary.

Best regards,
Eliot

LuminOre Copper Touch Proposed Product

Response to Chemistry Inquiries

Item to be registered:

Your company may or may not wish to register the 75% coating material. If you intend to provide this 75% material to other companies so that they may coat various substrate items and then make pesticidal public health claims you may want to register the 75% mup product.

As you intend to coat and market various items which will make public health claims, the coated items are required to be registered. The items can be registered under one registration number.

CSF

The proposed CSF containing the weight of the treated substrate is substantially acceptable. You indicated that you believe that separate CSFs will be required for each type of substrate due to their different weights, this is not the case. Your CSF containing the substrate is not being calculated on a weight basis, but a ratio basis. As you have indicated "Note: The copper concentration will remain constant at 3.8 oz/ft³ "

You should include a comprehensive list of the different types of substrate to be treated as an attachment to the CSF. Additionally, you must completely identify the Luminore Binding Agent. Provide the chemical identity, Cas#, and percent by weight of each component. Complete box 7 of the CSF with respect to the dried paint coating. The Agency notes that you have indicated wider than normal Certified Limit Ranges. You must submit a written rationale to justify the wider ranges. Indicate the purity of the source of copper used in your formulation. We are assuming from your draft CSF that the copper source is 100% pure. Based on this assumption the label ingredient statement would be 4.5% copper. Box 2 on the CSF must be completed.

Chemistry Data Requirements

The Part A product Chemistry Data requirements you have indicated are all required to support the registration of the coated item. Part B Physical/Chemical Properties of the dried coating can not be waived and must be added in your application. The Agency notes that all of the noted data requirements may not be applicable, and as such a rationale supporting the inapplicability of the requirement must be submitted.

Marshall Swindell/USEPA/AD/RMB1/PM 33

11/8/12

Watkins, Elizabeth

From: Powell, Wallace
Sent: Thursday, April 16, 2015 4:20 PM
To: Watkins, Elizabeth
Cc: Hicks, Karen
Subject: Technical screen for 88450-R and 88450-E acute toxicity data packages

Hi Elizabeth

The two DPs (426169 and 426172) pass the screen and are ready to go into review.

Wallace Powell
Antimicrobials Division
Office of Pesticide Programs
US Environmental Protection Agency
powell.wallace@epa.gov
703-308-6407

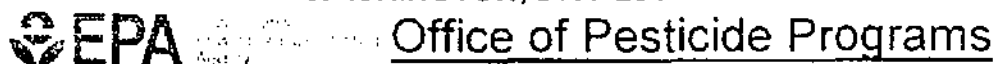
Chris (chemist) verbally agreed the
chem techscreen passed
Jiang

Technical Screen

NOTE: The efficacy studies refer to the product test lots as LuminOre Copper/Nickel

Technical Screen Conclusion: PASS			
EPA Reg#/File Symbol: 88450-R		E-Sub #: 7265	
DP Barcode: 426170		Submission #: 964333	
Product name: LuminOre CopperTouch Antimicrobial Surfaces		Registrant: Luminore, Inc.	
Reviewer's name: MRindal		Risk Manager: Elizabeth Watkins	
Agency Completion due date: 4/16/15		Completion Date: 4/16/15	
Formulation type: Liquid <input type="checkbox"/> ; Towelettes <input type="checkbox"/> ; Spray <input type="checkbox"/> ; Solid <input checked="" type="checkbox"/> ; Textile <input type="checkbox"/> ; Aerosol <input type="checkbox"/> ; Other _____			
Sterilant: <input type="checkbox"/> Disinfectant: <input type="checkbox"/> FC Sanitizer: <input type="checkbox"/> NF Sanitizer <input checked="" type="checkbox"/> Tuberculocide: <input type="checkbox"/> Virucide: <input type="checkbox"/>			
MRID(s): 495657-06, -07, -08, -09, -10, -11, One characterization assay, six efficacy studies			
PC Code(s)	Active Ingredient Names	% wt (label)	%LCL
022501	Copper*	85.0	82.3
	*Contains 3.8 oz. of copper per ft ²		
Label Claims:			
Product Lot(s)	Tested Concentration(s)	Tested at or Below LCL	
100214A	81.9	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
100114A	81.0	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
100114B	82.3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
		Yes <input type="checkbox"/>	No <input type="checkbox"/>
		Yes <input type="checkbox"/>	No <input type="checkbox"/>
		Yes <input type="checkbox"/>	No <input type="checkbox"/>
		Yes <input type="checkbox"/>	No <input type="checkbox"/>
		Yes <input type="checkbox"/>	No <input type="checkbox"/>
		Yes <input type="checkbox"/>	No <input type="checkbox"/>
Tested: RTU <input checked="" type="checkbox"/> Diluted <input type="checkbox"/>		Tested Dilution Rate: Not Applicable	
Certificate of Analysis: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		Performed by testing Lab: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
Test Lab: MicroBioTest Labs			
Comments:			

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**



Antimicrobials Division (AD)

July 31, 2015

EPA Reg#: 88450-R		DP Barcode: D426168 Submission #: 964333	
Product name: LuminOre CopperTouch Antimicrobial Surfaces		Registrant: LuminOre, Incorporated	
Reviewer's name: Chris Jiang		AD/PSB/CTT- Product Chemistry Review	
Agency due date: October 6, 2014		PSB received date: March 16, 2015	
CTT received date: March 18, 2015		Science due date: July 7, 2015	
Formulation type: TGAI : MUP : EUP X			
Integrated system: [X]		Non integrated system: []	Food use: [] Non food use: [X]
Action Code: A540		Date Completed:	
PC Code(s) :)	CAS #(s)	Active Ingredient Names	% wt (label)
025501	7440-50-8	Copper	85.0
Molecule structure (optional):			
Test Lab: Case Laboratories			
MRID(s): 49565701, 49565702, 49665703			
Approver: Karen P. Hicks		Approved date:	
Guideline: 830 Guidelines			
Comments:			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION
PREVENTION

June 31, 2015

MEMORANDUM

Subject: Review for 88450-R

From: Chris Jiang, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

To: John Hebert PM 33/Karen Leavy
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: LuminOre, Incorporated

Chris Jiang

don Blackburn for KPH

Formulation from Label

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Copper *	85.0
<u>Other Ingredients</u>	15.0
Total	100.00

*Contains 3.8 oz. of copper per ft²

BACKGROUND:

LuminOre, Incorporated has submitted a product chemistry package for an integrated end-use product for non-food-use. The package includes a data matrix, a label, a Confidential Statement of Formula for the basic formulation, and product chemistry requirements that are identified by the Agency as MRIDs 49565701, 49565702, and 49665703.

FINDINGS:

1. The concentration of the active ingredient on the Confidential Statement of Formula (CSF dated July 29, 2015 for the basic formulation) is consistent with the label declaration. This CSF supersedes all previous CSFs for the basic formulation.
2. All ingredients are approved for non-food use in pesticidal products.
3. The product identity and composition is **acceptable**.
4. The description of starting materials is **acceptable**.
5. The description of the production process is **acceptable**.
6. The description of the formulation process is **acceptable**.
7. The discussion of the formation of impurities is **acceptable**.
8. The preliminary analysis is **acceptable** in this case. The registrant has submitted five Certificates of Analysis for the preliminary analysis.
9. The certified limits are based on EPA standard certified limits and are **acceptable**.
10. The enforcement analytical method is **acceptable**.
11. The submittal of samples is **acceptable**.
12. The color, physical state, and odor are **acceptable** as the product is an odorless red solid powder.
13. The relative density is **acceptable** as the average value of this property was determined to be 4.0845 g/cm³ at 20.5 °C.
- 14.. The pH is **acceptable** as the product is not soluble or dispersible in water.
15. The oxidation/reduction potential is **acceptable** as copper is known to be a reducing agent.

- 16.. The flammability is **acceptable** as product does not contain combustible liquids.
17. The explodability is **acceptable** as the product is not potentially explosive.
18. A joint study for storage stability and corrosion characteristics is ongoing.
19. The viscosity is **acceptable** as product is a solid.
20. The miscibility is **acceptable** as the product is not to be diluted with petroleum solvents.
21. The dielectric breakdown voltage is **acceptable** as the product is not a liquid.

CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds the CSF for the basic formulation dated July 29, 2015 and the data for 88450-R to be acceptable for product chemistry, pending submission and acceptance of the joint study for storage stability and corrosion characteristics.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION


July 22, 2015


MEMORANDUM

Subject: Acute Toxicity Review for:

Data Package 426169
EPA File Symbol 88450-R
LuminOre CopperTouch Antimicrobial Surfaces

Data Package 426172
EPA File Symbol 88450-E
LuminOre CopperTouch Antimicrobial Copper Alloy Surfaces

From: Wallace Powell, Biologist 
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Through: Karen Hicks, Team Leader 
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

To: Jacqueline Hardy, PM 34/ Tom Luminello
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: LuminOre Incorporated

FORMULATION FROM PROPOSED LABEL:

LuminOre CopperTouch Antimicrobial Surfaces:

<u>Active Ingredient:</u>	<u>% by weight</u>
Copper (EPA PC Code 022501)	85.0
<u>Other Ingredient(s):</u>	<u>15.0</u>
Total:	100.0

LuminOre CopperTouch Antimicrobial Copper Alloy Surfaces:

<u>Active Ingredient:</u>	<u>% by weight</u>
Copper (EPA PC Code 022501)	62.5
<u>Other Ingredient(s):</u>	<u>37.5</u>
Total:	100.0

BACKGROUND

In support of registration for the subject products – LuminOre CopperTouch Antimicrobial Surfaces and LuminOre CopperTouch Antimicrobial Copper Alloy Surfaces – the applicant has submitted a data waiver request for acute oral, acute dermal, and acute inhalation toxicity, eye and dermal irritation, and dermal sensitization. The subject products are identified as copper-coated substrates. The substrates are items such as footboards, various handles, various kinds of knobs, door pulls, racks, handrails, various other items.

RECOMMENDATION

The waiver request is acceptable for all six data requirements. Based on the physical (solid, smooth coating) and chemical (primarily copper metallic) nature of the product, acute toxicity is of minimal concern. Metallic copper itself is of generally low acute toxicity; and exposure will be limited based on the product's physical nature.

After discussing, with two chemists in Antimicrobials Division, the submission and the supplemental information provided by Eliot Harrison (the applicant's representative) on 7/9/2015, PSB has no significant concern about the presence of the binder in the product. The material to which people will be exposed is primarily or entirely the copper (in LuminOre CopperTouch Antimicrobial Surfaces) or copper alloy (in LuminOre CopperTouch Antimicrobial Copper Alloy Surfaces). In consideration of the chemical nature of the binder, what little (if any) exposure there may be to the binder would not be problematic. Note that PSB offers these comments only in relation to the finished product, i.e., the copper- (or copper alloy-) coated substrate.

As indicated in the submitted waiver request, the product (the copper coated substrates) would not be well suited to acute toxicity testing.

As also indicated in the waiver request: "dermal and eye exposure will be no different than routine contact with common copper alloy articles." Basically the same could be said about dermal and eye acute effects as was said about dermal and eye "exposure".

The waiver request also correctly points out that waiver requests were previously granted for several products of the Copper Development Association (CDA) (EPA company number 82012) that are similar (though not identical) to the subject LuminOre products.

PSB's recommendation applies only if the pesticide product to be sold/distributed is indeed the copper coated substrate (as both products' application papers and both Data Package Beansheets indicate), not its precursors.

Also, PSB's recommendation for acute oral toxicity waiver applies only if all the coated substrate items are too large to be readily swallowed.

Summary:

The acute toxicity regulatory profile of LuminOre CopperTouch Antimicrobial Surfaces (EPA File Symbol 88450-R) and LuminOre CopperTouch Antimicrobial Copper Alloy Surfaces (EPA File Symbol 88450-R) is currently:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	Waiver requests: 49565704 (for EPA File Symbol 88450-R), 49565804 (for EPA File Symbol 88450-E)	IV	Waived
Acute Dermal Toxicity		IV	Waived
Acute Inhalation Toxicity		IV	Waived
Primary Eye Irritation		IV	Waived
Primary Dermal Irritation		IV	Waived
Dermal Sensitization		Non-sensitizer	Waived

Product Labeling:

No specific First Aid or human-hazard precautionary statements (or headings) are required except the front-panel statement "Keep Out of Reach of Children". The Agency PM may, in accordance with 40 CFR §156.66, decide whether to waive the requirement, and whether to approve its placement on other than the front panel.

The presence of the signal word is optional. If one is used, it must be "CAUTION".



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 16, 2015

MEMORANDUM

Subject: Efficacy Review for EPA File Symbol 88450-R, LuminOre Copper Touch
Antimicrobial Surfaces; DP Barcode: 426170

From: Marcus Rindal, Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

To: John Hebert PM 33/Karen Leavy
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: LuminOre, Incorporated
6060 Corte del Cedro
Carlsbad, CA 92011

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Copper*	85.0%
<u>Other Ingredients</u>	15.0%
Total	100.0%

* Contains 3.8 oz. of copper per ft²

I BACKGROUND

The product, LuminOre Copper Touch Antimicrobial Surfaces (EPA File Symbol 88450-R) is seeking a new registration to support the following sanitization claims:

- Hard surface as a sanitizer
- Continuous Bacterial Hard Surfaces as a Sanitizer
- Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces

Testing was conducted against 5 test organisms and each of the three sanitizer test methods. LuminOre Copper Touch Antimicrobial Surfaces is a copper coated substrate that provides continuous antimicrobial activity. The surface is a thin layer of copper which is bound to the substrate. The substrates proposed for use in the product are metal, plastic, and wood/wood composites. Several discussions were held between the registrant (LuminOre Inc.) and the Agency prior to the conduct of the efficacy studies. It was agreed that an aluminum-magnesium substrate should be used for all efficacy tests. In addition, the protocols used for LuminOre Copper Touch Antimicrobial Surfaces efficacy studies are the same protocols that were used for the efficacy studies performed with the copper alloys (Reg. No. 82021-2). Efficacy data were generated at MicroBioTest located at 105 Carpenter Drive in Sterling, VA, 20164.

The current data package contained a letter from the registrant's representative, Lewis & Harrison (dated February 10, 2015), EPA Form 8670-4 (Confidential Statement of Formula), Statement of No Data Confidentiality for each study, Good Laboratory Practices (GLP) Compliance Statement for each study, efficacy studies (MRID Nos. 495657-06 through 495657-11), and the proposed label.

II USE DIRECTIONS

The product is proposed to support claims for supplemental sanitizer with additional claims for continuous and... The product will be molded and cut for use in tables, desks, non-food contact counters, over the bed tables, bed side tables, hand rails, carts, doors, door push plates, towel bars, floor tiles, ceiling tiles, instrument casings and molded knobs, shopping carts, trays, soap holders, and light switches/plates. Directions on the proposed label provided the following instructions for the preparation, use, and maintenance of the product:

Clean and sanitize according to standard practice. Health care facilities must maintain the product in accordance with infection control guidelines. The use of this surface is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces. This surface has been shown to reduce microbial contamination, but does not necessarily prevent cross contamination.

This surface may be subject to recontamination and the level of active bacteria at any time will depend on the frequency and timing of recontamination and cleanliness of the surface (among other factors). In order to have proper antimicrobial effect, this product must be cleaned and maintained according to the directions for use.

Do not wax, paint, lacquer, varnish, or otherwise coat this product.

Routine cleaning to remove dirt and filth is necessary for good sanitation and to assure the effective antibacterial performance of this surface. Cleaning agents typically used for traditional hard, non-porous touch surfaces are permissible. The appropriate cleaning agent depends on the type of soiling and the measure of sanitization required. Normal tarnishing or wear of this surface will not impair antibacterial effectiveness.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Copper Alloy Surfaces as a Sanitizer: The effectiveness of copper alloy surfaces as sanitizers must be supported by data that show that the product (i.e., surface) will substantially reduce the numbers of test bacteria. Tests must be performed against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Results must show a bacterial reduction of at least 99.9 percent over the carrier quantitation control. The carrier quantitation control must yield a minimum geometric mean of 2.0×10^4 CFU/carrier. Claims for additional bacteria will be considered only if acceptable sanitizer efficacy is demonstrated for *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Products that are represented as residual self-sanitizers and/or continuous reduction sanitizers must demonstrate acceptable sanitizer efficacy before additional claims are considered. Agency standards and required label language are presented in EPA's "Test Method for Efficacy of Copper Alloy Surfaces as a Sanitizer." To support a supplemental sanitization claim on a copper alloy surface, a 99.9% reduction in numbers of the test organism(s) must be obtained as compared to the carrier quantitation control. Efficacy data can support the claim "kills greater than 99.9% of bacteria* within two hours (* Includes list of tested organisms). Claims are limited to indoor, hard, non-porous surfaces where cleaning practices are consistent. The following language is required on the registered products, the use of a copper surface is a supplement to and not a substitute for standard infection control practices; user must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces. The copper surface material has been shown to reduce microbial contamination, but does not necessarily prevent cross contamination.

Residual Self-Sanitizing Activity of Copper Alloy Surfaces: The effectiveness of copper alloy surfaces to provide residual self-sanitizing activity must be supported by data that show that the product (i.e., surface) will substantially reduce the number of test bacteria. An initial sanitizer evaluation, a simulated wear-and-re-inoculation evaluation, and a final sanitizer evaluation must be performed. Tests must be performed against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Results must show a reduction of the total number of organisms by at least 99.9 percent on the surface within/for the prescribed exposure time. The control plates must show a minimum of 2×10^4 CFU/carrier for the test to be considered valid. Claims for additional bacteria will be considered only if acceptable sanitizer efficacy is demonstrated for *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Products that are represented as residual self-sanitizers and/or continuous reduction sanitizers must demonstrate acceptable sanitizer efficacy before additional claims are considered. Agency standards and required label language are presented in EPA's "Test Method for Residual Self-Sanitizing Activity of Copper Alloy Surfaces." To be defined as a residual self-sanitizer, the test material must reduce the total number of organisms by at least 99.9% on the surface within the prescribed exposure time.

Claims are limited to indoor, hard, non-porous surfaces where cleaning practices are consistent. The acceptable claim indicates the surface kills greater than 99.9% of bacteria* for 24 hours.

*Includes list of tested organisms.

Copper Alloy Surfaces as a Continuous Reduction Sanitizer: The effectiveness of copper alloy surfaces to provide continuous reduction of bacterial contamination must be supported by data that show that the product (i.e., surface) will substantially reduce the number of test bacteria. Tests must be performed against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Results must show a bacterial reduction of at least 90 percent over the carrier quantitation control at all recovery times over the 24-hour inoculation and exposure period. The carrier quantitation control must yield a minimum geometric mean of 2.0×10^4 CFU/carrier. Claims for additional bacteria will be considered only if acceptable sanitizer efficacy is demonstrated for *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Products that are represented as residual self-sanitizers and/or continuous reduction sanitizers must demonstrate acceptable sanitizer efficacy before additional claims are considered. Agency standards and required label language are presented in EPA's "Test Method for the Continuous Reduction of Bacterial Contamination on Copper Alloy Surfaces."

General Considerations Regarding Claims and Labeling

The following language is required on the registered products, the use of a copper surface is a supplement to and not a substitute for standard infection control practices; user must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces. The copper surface material has been shown to reduce microbial contamination, but does not necessarily prevent cross contamination.

Proper Care and Use of Antimicrobial Copper Surfaces: The use of copper surfaces does not replace standard infection control procedures and good hygienic practices. Antimicrobial copper surfaces must be cleaned and sanitized according to standard practice. Health care facilities must maintain the product in accordance with infection control guidelines; users must continue to follow all current infection control practices, including those practices related to disinfection of environmental surfaces.

Cleaning Directions: Routine cleaning to remove dirt and filth is necessary for good sanitization and to assure the effective antibacterial performance of the copper surfaces. Cleaning agents typically used for traditional touching surfaces are permissible; the appropriate cleaning agent depends on the type of soiling and the measure of sanitization required.

This product must not be waxed, painted, lacquered, varnished, or otherwise coated.

IV SYNOPSIS OF SUBMITTED EFFICACY STUDIES

1. **MRID No. 495657-06, "Efficacy Evaluation of Copper Enhanced Hard Surfaces as a Sanitizer" using LuminOre Copper by Angela Hollingsworth. Study Completion Date – February 4, 2015. Laboratory Project Identification Number: 872-101.**

The product was tested against *Staphylococcus aureus* (ATCC# 6538) and *Enterobacter aerogenes* (ATCC# 13048). Three lots (Lot Nos. 100214A, 100114A, and 100114B) of the product, LuminOre Copper were tested using Protocol No. LUM.1a.06.15.14 (copy provided). A control sample, designated as Non Treated Coupons and assigned DS No. E532, was provided and included in the test system. The test system included 5 carrier replicates/lot and 3 control carrier replicates per test organism. Organic soil described as 0.25 mL of heat-inactivated fetal bovine serum plus 0.05 mL of Triton X-100 solution added to 4.70 mL of the bacteria suspension per 5 mL to yield at 5% FBS and 0.01% Triton X-100 soil load. An aliquot, 0.02 mL, of the inoculum was placed onto each sterile and control article carrier. The inoculum was spread to within approximately 1/8" of the edge of the carrier. The carriers were allowed to dry with lids ajar for 30 minutes under ambient conditions. The contact time began immediately after drying. At the conclusion of the 120 minute contact time, each carrier was transferred to a jar containing 20 mL of neutralizer. Each jar was sonicated for five minutes and then rotated by hand to mix. Within one hour after sonication, serial dilutions were prepared using PBS (10^{-1} and 10^{-4}). Duplicate 1.0 mL aliquots from each jar/dilution (10^0 - 10^{-4}) were plated using TSA pour plates. For *S. aureus*, plates were incubated for 48±4 hours at 35-37°C; for *E. aerogenes* plates were incubated for 48±4 hours at 25-30°C. Controls included those for carrier quantitation, purity, sterility, viability, neutralizer effectiveness control, and microorganism confirmation.

2. **MRID No. 495657-07, "Efficacy Evaluation of Copper Enhanced Hard Surfaces as a Sanitizer Supplemental" using LuminOre Copper by Angela Hollingsworth. Study Completion Date – February 4, 2015. Laboratory Project Identification Number: 872-103.**

The product was tested against *Pseudomonas aeruginosa* (ATCC# 15442), Methicillin Resistant *Staphylococcus aureus* (ATCC# 33592) and *Escherichia coli* O157:H7 (ATCC# 35150). Two lots (Lot Nos. 100214A and 100114A) of the product, LuminOre Copper were tested using Protocol No. LUM.4a.06.15.14 (copy provided). A control sample, designated as Non Treated Coupons and assigned DS No. E532, was provided and included in the test system. The test system included 5 carrier replicates/lot and 3 control carrier replicates per test organism. Organic soil described as 0.25 mL of heat-inactivated fetal bovine serum plus 0.05 mL of Triton X-100 solution added to 4.70 mL of the bacteria suspension per 5 mL to yield at 5% FBS and 0.01% Triton X-100 soil load. An aliquot, 0.02 mL, of the inoculum was placed onto each sterile and control article carrier. The inoculum was spread to within approximately 1/8" of the edge of the carrier. The carriers were allowed to dry with lids ajar for 30 minutes under ambient conditions. The contact time began immediately after drying. At the conclusion of the 120 minute contact time, each carrier was transferred to a jar containing 20 mL of neutralizer. Each jar was sonicated for five minutes and then rotated by hand to mix. Within one hour after sonication, serial dilutions were prepared using PBS (10^{-1} and 10^{-4}). Duplicate 1.0 mL aliquots from each jar/dilution (10^0 - 10^{-4}) were plated using TSA pour plates. For all three test organisms, plates were incubated for 48±4 hours at 35-37°C. Controls included those

for carrier quantitation, purity, sterility, viability, neutralizer effectiveness control, and microorganism confirmation.

3. MRID No. 495657-08, "Efficacy Evaluation of Continuous Bacterial Contamination Reduction on Enhanced Hard Surfaces as a Sanitizer," using LuminOre Copper by Angela Hollingsworth. Study Completion Date – February 4, 2015. Laboratory Project Identification Number: 872-105.

The product was tested against *Staphylococcus aureus* (ATCC# 6538) and *Enterobacter aerogenes* (ATCC# 13048). Three lots (Lot Nos. 100214A, 100114A, and 100114B) of the product, LuminOre Copper were tested using Protocol No. LUM.2b.06.15.14 (copy provided). A control sample, designated as Non Treated Coupons and assigned DS No. E532, was provided and included in the test system. The test system included 5 carrier replicates/lot and 3 control carrier replicates per test organism. Organic soil described as 0.25 mL of heat-inactivated fetal bovine serum plus 0.05 mL of Triton X-100 solution added to 4.70 mL of the bacteria suspension per 5 mL to yield at 5% FBS and 0.01% Triton X-100 soil load. All test and control surfaces were inoculated at staggered intervals with 5 µL of the test organism. The inoculum was spread to within approximately 1/8" of the edge of the carrier. The contact time initiated immediately after inoculation. This initial inoculation was considered as "time zero". Carriers were re-inoculated in the same manner at 3, 6, 9, 12, 15, 18, and 21 hours. The carriers were dried at ambient conditions for the duration of exposure. The exposure period began with the initial "time-zero" inoculation. The sets not removed for quantitative recovery were inoculated in the same manner at 3, 6, 9, 12, 15, 18, and 21 hours post "time-zero" inoculation. The sets for quantitative recovery were removed at 2 (single inoculation), 6 (two inoculations), 12 (four inoculations), 18 (six inoculations), and 24 (8 inoculations) hours. At the conclusion of the applicable contact times for each set of surfaces, each carrier was transferred to a jar containing 20 mL of neutralizer at the appropriate staggered intervals. Each jar was sonicated for five minutes and then rotated by hand to mix. Within one hour after sonication, serial dilutions were prepared using PBS (10^{-1} – 10^{-4}). Duplicate 1.0 mL aliquots from each jar/dilution (10^0 – 10^{-4}) were plated using TSA pour plates. For *S. aureus*, plates were incubated for 48±4 hours at 35-37°C; for *E. aerogenes* plates were incubated for 48±4 hours at 25-30°C. Controls included those for carrier quantitation, purity, sterility, viability, neutralizer effectiveness control, and microorganism confirmation.

4. MRID No. 495657-09, "Efficacy Evaluation of Continuous Bacterial Contamination Reduction on Enhanced Hard Surfaces as a Sanitizer Supplemental," using LuminOre Copper by Angela Hollingsworth. Study Completion Date – February 4, 2015. Laboratory Project Identification Number: 872-109.

The product was tested against *Pseudomonas aeruginosa* (ATCC# 15442), Methicillin Resistant *Staphylococcus aureus* (ATCC# 33592) and *Escherichia coli* O157:H7 (ATCC# 35150). Two lots (Lot Nos. 100214A and 100114A) of the product, LuminOre Copper were tested using Protocol No. LUM.5a.06.15.14 (copy provided). A control sample, designated as Non Treated Coupons and assigned DS No. E532, was provided and included in the test system. The test system included 5 carrier replicates/lot and 3 control carrier replicates per test organism. Organic soil described as 0.25 mL of heat-inactivated fetal bovine serum plus 0.05 mL of Triton X-100 solution added to 4.70 mL of the bacteria suspension per 5 mL to yield at 5% FBS and 0.01% Triton X-100 soil load. All test and control surfaces were inoculated at staggered intervals with 5 µL of the

test organism. The inoculum was spread to within approximately $\frac{1}{8}$ " of the edge of the carrier. The contact time initiated immediately after inoculation. This initial inoculation was considered as "time zero". Carriers were re-inoculated in the same manner at 3, 6, 9, 12, 15, 18, and 21 hours. The carriers were dried at ambient conditions for the duration of exposure. The exposure period began with the initial "time-zero" inoculation. The sets not removed for quantitative recovery were inoculated in the same manner at 3, 6, 9, 12, 15, 18, and 21 hours post "time-zero" inoculation. The sets for quantitative recovery were removed at 2 (single inoculation), 6 (two inoculations), 12 (four inoculations), 18 (six inoculations), and 24 (8 inoculations) hours. At the conclusion of the applicable contact times for each set of surfaces, each carrier was transferred to a jar containing 20 mL of neutralizer at the appropriate staggered intervals. Each jar was sonicated for five minutes and then rotated by hand to mix. Within one hour after sonication, serial dilutions were prepared using PBS (10^{-1} – 10^{-4}). Duplicate 1.0 mL aliquots from each jar/dilution (10^0 – 10^{-4}) were plated using TSA pour plates. Plates were incubated for 48 ± 4 hours at 35 – 37°C . Controls included those for carrier quantitation, purity, sterility, viability, neutralizer effectiveness control, and microorganism confirmation.

5. MRID No. 495657-10, "Efficacy Evaluation of Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces," using LuminOre Copper by Angela Hollingsworth. Study Completion Date: February 4, 2015. Laboratory Project Identification Number: 872-107.

The product was tested against *Staphylococcus aureus* (ATCC# 6538) and *Enterobacter aerogenes* (ATCC# 13048). Three lots (Lot Nos. 100214A, 100114A, and 100114B) of the product, LuminOre Copper were tested using Protocol No. LUM.3a.06.15.14 (copy provided). A control sample, designated as Non Treated Coupons and assigned DS No. E532, was provided and included in the test system. The test system included 4 carrier replicates/lot and 8 control carrier replicates per test organism (4 initial carriers and 4 final carriers). Organic soil described as 0.25 mL of heat-inactivated fetal bovine serum plus 0.05 mL of Triton X-100 solution added to 4.70 mL of the bacteria suspension per 5 mL to yield at 5% FBS and 0.01% Triton X-100 challenge.

Initial Sanitizer Test. Each lot of the test surface carrier and control was inoculated with 10 μL of the prepared initial sanitizer inoculum. Carriers were allowed to dry for 30-40 minutes at 35 – 37°C at 38-42% relative humidity. Immediately after drying, the 120 minute contact time was initiated. At the conclusion of the contact time, each carrier was transferred to a jar containing 30 mL of neutralizer at the appropriate staggered intervals. Each jar was subsequently sonicated for 20 ± 2 seconds. The samples were then mixed on an orbital shaker for 3-4 minutes at 250 rpm. Serial dilution were then prepared using sterile deionized water. Duplicate 1.0 mL aliquots from each jar/dilution (10^0 – 10^{-2}) for the test carriers and (10^2 – 10^{-4}) for the control carriers were plated using TSA pour plates. *S. aureus* plates were incubated for 48 ± 4 hours at 35 – 37°C . *E. aerogenes* plates were incubated for 48 ± 4 hours at 25 – 30°C .

Simulated Wear and Reinoculation. Prior to inoculation, the abrasion tester was set to a speed of 2.25 –2.50 for total surface contact time of approximately 4-5 seconds for one complete cycle. The speed was measured with a stopwatch, and the machine's cycle was calibrated by adjusting the number counter to 1, 5, 10, and 20 and verifying cycle time. It will be set so that one pass on the abrasion tester with the surfaces is equal to a contact time of approximately 2 seconds. A wear cycle was identified as one pass to the left and a return pass to the right on the Gardner scrubber with an abrasion boat fitted with a foam

liner and dry cotton cloth. The weight of the fully assembled weight boat was determined to be $1084 \pm 1\text{g}$ prior to use. For each lot of the test surface, per microorganism, four carriers will be inoculated at staggered intervals with 0.01 mL of the prepared simulated wears inoculum using a calibrated pipette. The inoculum will be spread to within approximately $1/8^{\text{th}}$ inch of the edge of the carrier and the carriers will be allowed to dry for 30-40 minutes at $35\text{-}37^{\circ}\text{C}$. These inoculation and drying procedures will be designated as "reinoculated and drying." To initiate the wear cycles, each carrier was subjected to a dry wear cycle using the Gardco Washability and Wear Tester and the fully assembled weight boat. Fifteen (15) minutes after the initial wear cycle, each carrier was re-inoculated and dried at ambient temperature. Each carrier was then subjected to a wet wear cycle using the Gardco Washability and Wear Tester and the fully assembled weight boat. The fully assembled weight boat was sprayed for one second with sterile deionized water using a Preval sprayer from a distance of $75 \pm 1\text{ cm}$ for not more than one second. At least 15 minutes after the secondary wear cycle, each carrier was re-inoculated with 10 μL of test organism and dried. Each carrier was subjected to alternating dry and wet wears until a total of 11 reinoculations and 12 wear cycles had been performed (Table 1 in the Protocol, pg 27 of 41).

Final Sanitizer Evaluation. Conducted at the completion of the wear cycles and reinoculations were identical to the Initial Sanitizer Evaluation. For each lot of the test surface, per microorganism, four carriers and four control surface carriers (per microorganism) will be inoculated at staggered intervals with 0.01 mL of the prepared final sanitizer inoculum using a calibrated pipette. The inoculum will be spread to within approximately $1/8^{\text{th}}$ inch of the edge of the carrier and the carriers will be allowed to dry for 30-40 minutes at $35\text{-}37^{\circ}\text{C}$. Immediately after drying, the 2 hour contact time will begin at ambient temperature, after which each carrier will be transferred to a jar containing 30 mL of neutralizer at the appropriate staggered intervals. Each jar was subsequently sonicated for 20 ± 2 seconds. The samples were then mixed on an orbital shaker for 3-4 minutes at 250 rpm. Serial dilution were then prepared using sterile deionized water. Duplicate 1.0 mL aliquots from each jar/dilution ($10^0 - 10^{-2}$) for the test carriers and ($10^2 - 10^{-4}$) for the control carriers were plated using TSA pour plates. *S. aureus* plates were incubated for 48 ± 4 hours at $35\text{-}37^{\circ}\text{C}$. *E. aerogenes* plates were incubated for 48 ± 4 hours at $25\text{-}30^{\circ}\text{C}$.

Controls included those for purity, sterility, inoculum confirmation counts, viability, neutralizer effectiveness, and microorganism confirmation.

6. MRID No. 495657-11, "Efficacy Evaluation of Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces - Supplemental," using LuminOre Copper by Angela Hollingsworth. Study Completion Date: February 4, 2015. Laboratory Project Identification Number: 872-111.

The product was tested against *Pseudomonas aeruginosa* (ATCC# 15442), Methicillin Resistant *Staphylococcus aureus* (ATCC# 33592) and *Escherichia coli* O157:H7 (ATCC# 35150). Two lots (Lot Nos. 100214A and 100114A) of the product, LuminOre Copper were tested using Protocol No. LUM.6a.06.15.14 (copy provided). A control sample, designated as Non Treated Coupons and assigned DS No. E532, was provided and included in the test system. The test system included 4 carrier replicates/lot and 8 control carrier replicates per test organism (4 initial carriers and 4 final carriers). Organic soil described as 0.25 mL of heat-inactivated fetal bovine serum plus 0.05 mL of

Triton X-100 solution added to 4.70 mL of the bacteria suspension per 5 mL to yield at 5% FBS and 0.01% Triton X-100 challenge.

Initial Sanitizer Test. Each lot of the test surface carrier and control was inoculated with 10 μ L of the prepared initial sanitizer inoculum. Carriers were allowed to dry for 30-40 minutes at 36°C at 35-37% relative humidity. Immediately after drying, the 120 minute contact time was initiated. At the conclusion of the contact time, each carrier was transferred to a jar containing 30 mL of neutralizer at the appropriate staggered intervals. Each jar was subsequently sonicated for 20 \pm 2 seconds. The samples were then mixed on an orbital shaker for 3-4 minutes at 250 rpm. Serial dilution were then prepared using sterile deionized water. Duplicate 1.0 mL aliquots from each jar/dilution ($10^0 - 10^{-2}$) for the test carriers and ($10^2 - 10^{-4}$) for the control carriers were plated using TSA pour plates. All test plates were incubated for 48 \pm 4 hours at 35-37°C.

Simulated Wear and Reinoculation. Prior to inoculation, the abrasion tester was set to a speed of 2.25 -2.50 for total surface contact time of approximately 4-5 seconds for one complete cycle. The speed was measured with a stopwatch, and the machine's cycle was calibrated by adjusting the number counter to 1, 5, 10, and 20 and verifying cycle time. It will be set so that one pass on the abrasion tester with the surfaces is equal to a contact time of approximately 2 seconds. A wear cycle was identified as one pass to the left and a return pass to the right on the Gardner scrubber with an abrasion boat fitted with a foam liner and dry cotton cloth. The weight of the fully assembled weight boat was determined to be 1084 \pm 1g prior to use. For each lot of the test surface, per microorganism, four carriers will be inoculated at staggered intervals with 0.01 mL of the prepared simulated wears inoculum using a calibrated pipette. The inoculum will be spread to within approximately 1/8th inch of the edge of the carrier and the carriers will be allowed to dry for 30-40 minutes at 35-37°C. These inoculation and drying procedures will be designated as "reinoculated and drying." To initiate the wear cycles, each carrier was subjected to a dry wear cycle using the Gardco Washability and Wear Tester and the fully assembled weight boat. Fifteen (15) minutes after the initial wear cycle, each carrier was re-inoculated and dried as previously described. Each carrier was then subjected to a wet wear cycle using the Gardco Washability and Wear Tester and the fully assembled weight boat. The fully assembled weight boat was sprayed for one second with sterile deionized water using a Preval sprayer from a distance of 75 \pm 1 cm for not more than one second. At least 15 minutes after the secondary wear cycle, each carrier was re-inoculated with 10 μ L of test organism and dried. Each carrier was subjected to alternating dry and wet wears until a total of 11 reinoculations and 12 wear cycles had been performed (Table 1 in the Protocol, pg 26 of 39).

Final Sanitizer Evaluation. Conducted at the completion of the wear cycles and reinoculations were identical to the Initial Sanitizer Evaluation. For each lot of the test surface, per microorganism, four carriers and four control surface carriers (per microorganism) will be inoculated at staggered intervals with 0.01 mL of the prepared final sanitizer inoculum using a calibrated pipette. The inoculum will be spread to within approximately 1/8th inch of the edge of the carrier and the carriers will be allowed to dry for 30-40 minutes at 35-37°C. Immediately after drying, the 2 hour contact time will begin at ambient temperature, after which each carrier will be transferred to a jar containing 30 mL of neutralizer at the appropriate staggered intervals. Each jar was subsequently sonicated for 20 \pm 2 seconds. The samples were then mixed on an orbital shaker for 3-4 minutes at 250 rpm. Serial dilution were then prepared using sterile deionized water. Duplicate 1.0 mL aliquots from each jar/dilution ($10^0 - 10^{-2}$) for the test carriers and ($10^2 -$

10⁻⁴) for the control carriers were plated using TSA pour plates. All test plates were incubated for 48±4 hours at 35-37°C.

Controls included those for purity, sterility, inoculum confirmation counts, viability, neutralizer effectiveness, and microorganism confirmation.

V RESULTS

Copper Enhanced Hard Surfaces as a Sanitizer

MRID Number	Organism	Lot No.	Average CFU/carrier	Average Organism Recovered (CFU/carrier)	Percent Reduction
495657-06	<i>Staphylococcus aureus</i>	100214A	5.4×10 ⁵	<1.0×10 ⁰	>99.9
		100114A		<1.0×10 ⁰	>99.9
		100114B		<1.0×10 ⁰	>99.9
	<i>Enterobacter aerogenes</i>	100214A	1.3×10 ⁶	<1.0×10 ⁰	>99.9
		100114A		<1.0×10 ⁰	>99.9
		100114B		<1.0×10 ⁰	>99.9
495657-07	<i>Pseudomonas aeruginosa</i>	100214A	5.7×10 ⁶	3,442	>99.9
		100114A		574	>99.9
	<i>Staphylococcus aureus</i> (MRSA)*	100214A	1.6×10 ⁶	144	>99.9
		100114A		154	>99.9
	<i>Escherichia coli</i> O157:H7	100214A	3.1×10 ⁶	≤8.6	>99.9
		100114A		≤6.6	>99.9

* Methicillin Resistant

Continuous Bacterial Contamination Reduction on Enhanced Hard Surfaces as Sanitizer

MRID Number	Organism	Contact Time	Lot No.	Average CFU/carrier		Average Percent Reduction
				Carrier Count	Organism Recovered	
495657-08	<i>Staphylococcus aureus</i>	2 Hours	100214A	1.3×10 ⁵	<1.0×10 ⁰	>99.9
			100114A		<1.0×10 ⁰	>99.9
			100114B		<1.0×10 ⁰	>99.9
		6 Hours	100214A	2.4×10 ⁵	<1.0×10 ⁰	>99.9
			100114A		<1.0×10 ⁰	>99.9
			100114B		<1.0×10 ⁰	>99.9
		12 Hours	100214A	4.0×10 ⁵	<1.0×10 ⁰	>99.9
			100114A		<1.0×10 ⁰	>99.9
			100114B		<1.0×10 ⁰	>99.9
		18 Hours	100214A	5.4×10 ⁵	<1.0×10 ⁰	>99.9
			100114A		<1.0×10 ⁰	>99.9
			100114B		<1.0×10 ⁰	>99.9
		24 Hours	100214A	5.6×10 ⁵	<1.0×10 ⁰	>99.9
			100114A		<1.0×10 ⁰	>99.9
			100114B		<1.0×10 ⁰	>99.9

Continuous Bacterial Contamination Reduction on Enhanced Hard Surfaces as Sanitizer

MRID Number	Organism	Contact Time	Lot No.	Average CFU/carrier		Average Percent Reduction
				Carrier Count	Organism Recovered	
495657-08	<i>Enterobacter aerogenes</i>	2 Hours	100214A	7.5×10^5	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
			100114B		$<1.0 \times 10^0$	>99.9
		6 Hours	100214A	1.3×10^6	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
			100114B		$<1.0 \times 10^0$	>99.9
		12 Hours	100214A	2.3×10^6	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
			100114B		$<1.0 \times 10^0$	>99.9
		18 Hours	100214A	1.6×10^6	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
			100114B		$<1.0 \times 10^0$	>99.9
		24 Hours	100214A	1.3×10^6	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
			100114B		$<1.0 \times 10^0$	>99.9

Continuous Bacterial Contamination Reduction on Enhanced Hard Surfaces as Sanitizer

MRID Number	Organism	Contact Time	Lot No.	Average CFU/carrier		Average Percent Reduction
				Carrier Count	Organism Recovered	
495657-09	<i>Pseudomonas aeruginosa</i>	2 Hours	100214A	4.4×10^5	<21	>99.9
			100114A		<40.6	>99.9
		6 Hours	100214A	4.8×10^5	<92.8	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
		12 Hours	100214A	8.4×10^4	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
		18 Hours	100214A	1.1×10^6	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
		24 Hours	100214A	9.2×10^5	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9

Continuous Bacterial Contamination Reduction on Enhanced Hard Surfaces as Sanitizer

MRID Number	Organism	Contact Time	Lot No.	Average CFU/carrier		Average Percent Reduction
				Carrier Count	Organism Recovered	
495657-09	<i>Staphylococcus aureus</i> (MRSA)* *Methicillin Resistant	2 Hours	100214A	3.9×10^5	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
		6 Hours	100214A	9.0×10^6	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
		12 Hours	100214A	6.8×10^6	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
		18 Hours	100214A	3.1×10^6	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
		24 Hours	100214A	9.1×10^6	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9

Continuous Bacterial Contamination Reduction on Enhanced Hard Surfaces as Sanitizer

MRID Number	Organism	Contact Time	Lot No.	Average CFU/carrier		Average Percent Reduction
				Carrier Count	Organism Recovered	
495657-09	<i>Escherichia coli</i> O157:H7	2 Hours	100214A	8.9×10^5	<52.8	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
		6 Hours	100214A	1.5×10^6	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
		12 Hours	100214A	7.9×10^5	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
		18 Hours	100214A	2.4×10^6	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
		24 Hours	100214A	1.7×10^6	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9

Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces

MRID Number	Organism	Evaluation	Lot No.	Average CFU/carrier		Average Percent Reduction
				Carrier Count	Organism Recovered	
495657-10	<i>Staphylococcus aureus</i>	Initial	100214A	1.3×10^5	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
			100114B		$<1.0 \times 10^0$	>99.9
		Final	100214A	1.7×10^5	<113.5	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
			100114B		$<1.0 \times 10^0$	>99.9

Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces

MRID Number	Organism	Evaluation	Lot No.	Average CFU/carrier		Average Percent Reduction
				Carrier Count	Organism Recovered	
495657-10	<i>Enterobacter aerogenes</i>	Initial	100214A	9.1×10^5	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
			100114B		$<1.0 \times 10^0$	>99.9
		Final	100214A	2.2×10^5	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
			100114B		$<1.0 \times 10^0$	>99.9

Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces

MRID Number	Organism	Evaluation	Lot No.	Average CFU/carrier		Average Percent Reduction
				Carrier Count	Organism Recovered	
495657-11	<i>Pseudomonas aeruginosa</i>	Initial	100214A	1.1×10^6	235	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
		Final	100214A	1.4×10^6	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9

Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces

MRID Number	Organism	Evaluation	Lot No.	Average CFU/carrier		Average Percent Reduction
				Carrier Count	Organism Recovered	
495657-11	<i>Staphylococcus aureus</i> (MRSA)* *Methicillin Resistant	Initial	100214A	4.9×10^5	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9
		Final	100214A	5.6×10^5	23.5	>99.9
			100114A		$<1.0 \times 10^0$	>99.9

Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces

MRID Number	Organism	Evaluation	Lot No.	Average CFU/carrier		Average Percent Reduction
				Carrier Count	Organism Recovered	
495657-11	<i>Escherichia coli</i> O157:H7	Initial	100214A	1.1×10^6	19.5	>99.9
			100114A		8.25	>99.9
		Final	100214A	8.0×10^5	$<1.0 \times 10^0$	>99.9
			100114A		$<1.0 \times 10^0$	>99.9

VI CONCLUSIONS

1. The label claims the product continuously reduces bacteria [sic] contamination, achieving 99.9% reduction within 2 hours of exposure. This claim is acceptable as it is supported by the submitted data. Change "bacteria" to adj. form – bacterial.
2. The label claims that the product kills greater than 99.9% of Gram-negative and Gram-positive bacteria within 2 hours of exposure. This claim is acceptable as it is supported by the submitted data.

3. The label claims that the product delivers continuous and ongoing antibacterial action, remaining effective in killing greater than 99.9% of bacteria within 2 hours. This claim should be clarified to distinguish between continuous reduction (kill requirement of at least 90% reduction over 24 hours) and surface as a sanitizer (kill requirement of at least 99.9% over 2 hours).
4. The label claims that the product kills greater than 99.9% of bacteria within 2 hours and continues to kill 99% of bacteria even after repeated contaminations. This claim is acceptable as it is supported by the submitted data.

Label Comments:

- Claims are limited to indoor (i.e., hard, non-porous) surfaces where cleaning practices are consistent. All "Product is for indoor use only where cleaning practices are consistent."
- Pg. 3: Remove reference to "knurled" knobs.

Important Note: This product registration WILL require additional efficacy testing pending finalization of the copper surface protocol(s) by the Agency.



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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address and Telephone Number LuminOre Inc., 6060 Corte del Cedro, Carlsbad, CA 92011	EPA Registration Number/ File Symbol 88450-
Active Ingredient(s) and/or representative test compound(s): Metallic Copper	Date February 10, 2015
General use pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor, Non-Food	Product Name LuminOre CopperTouch Antimicrobial Surfaces

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
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SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data Call-In Notice is supported by all data submitted or cited in the application for registration, the form for reregistration, or this Data Call-In response. In addition, if cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original submitter or that I have obtained the written permission of the original submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the written permission of the original data submitter to use this study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 2/10/2015	Typed or Printed Name and Title Eliot Harrison, Agent for LuminOre Inc. e-Submission
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DATA MATRIX

Date February 11, 2015		EPA Reg. No./File Symbol 88450-		Page 1 of 5	
Applicant's/Registrant's Name & Address: LuminOre Incorporated, 6060 Corte del Cedro, Carlsbad, CA 92011		Product LuminOre CopperTouch Antimicrobial Copper Alloy Surfaces			
Ingredient(s): Elemental Copper (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT CHEMISTRY					
830.1550	Product Identity and Composition	49565801	LuminOre Inc. (EPA Co. # 88450)	OWN	Volume 1
830.1600	Description of Beginning Materials	49565801	LuminOre Inc. (EPA Co. # 88450)	OWN	Volume 1
830.1670	Description of Formulation Process	49565801	LuminOre Inc. (EPA Co. # 88450)	OWN	Volume 1
830.1700	Preliminary Analysis	49565801	LuminOre Inc. (EPA Co. # 88450)	OWN	Volume 1
830.1750	Certified Limits	49565801	LuminOre Inc. (EPA Co. # 88450)	OWN	Volume 1
830.1800	Enforcement Analytical Method	49565801	LuminOre Inc. (EPA Co. # 88450)	OWN	Volume 1
830.6302	Color	49565802 49565803	LuminOre Inc. (EPA Co. # 88450)	OWN	Volumes 2 and 3
830.6303	Physical State	49565802 49565803	LuminOre Inc. (EPA Co. # 88450)	OWN	Volumes 2 and 3
830.6304	Odor	49565802 49565803	LuminOre Inc. (EPA Co. # 88450)	OWN	Volumes 2 and 3
830.6313	Stability	Not Applicable	-----		Volume 2
830.6314	Oxidation/reduction activity	49565802	LuminOre Inc. (EPA Co. # 88450)	PL	Footnote 1 & Volume 2
830.6315	Flammability	Not Applicable	-----		Footnote 2 & Volume 2
830.6316	Explosibility	Not Applicable	-----		Footnote 3 & Volume 1
830.6317	Storage Stability	-----			Footnote 4
830.6319	Miscibility	Not Applicable	-----		Footnote 5 & Volume 2
830.6320	Corrosion Characteristics	-----			Footnote 4
830.6321	Dielectric Breakdown Voltage	Not Applicable	-----		Footnote 6 & Volume 2
830.7000	pH	Not Applicable	-----		Footnote 7 &

Signature

Name and Title: Eliot Harrison, Agent for LuminOre Inc.

Date
February 11, 2015



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DATA MATRIX

Date February 11, 2015	EPA Reg. No./File Symbol 88450-	Page 2 of 5
Applicant's/Registrant's Name & Address: LuminOre Incorporated, 6060 Corte del Cedro, Carlsbad, CA 92011	Product LuminOre CopperTouch Antimicrobial Copper Alloy Surfaces	

Ingredient(s): Elemental Copper (PC Code 22501)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Volume 2
830.7050	UV/Visible Light Absorption	49565802	LuminOre Inc. (EPA Co. # 88450)	PL	Volume 2
830.7100	Viscosity	Not Applicable	-----		Footnote 8 & Volume 2
830.7200	Melting Point	49565802	LuminOre Inc. (EPA Co. # 88450)	PL	Volume 2
830.7220	Boiling Point	Not Applicable	-----		Footnote 9 & Volume 2
830.7300	Density	49565802 49565803	LuminOre Inc. (EPA Co. # 88450)	OWN	Volumes 2 & 3
830.7520	Particle Size	49565802	LuminOre Inc. (EPA Co. # 88450)	OWN	Volume 2
830.7370	Dissociation Constant	Not Applicable	-----		Footnote 10 & Volume 2
830.7550	Partition Coefficient	Not Applicable	-----		Footnote 11 & Volume 2
830.7840	Water Solubility	49565802	LuminOre Inc. (EPA Co. # 88450)	PL	Volume 2
830.7950	Vapor Pressure	Not Applicable	-----		Footnote 12 & Volume 2

TOXICOLOGY

870.1100	Acute Oral Toxicity	49565804	LuminOre Inc. (EPA Co. # 88450)	OWN	Footnote 13 & Volume 4
870.1200	Acute Dermal Toxicity	49565804	LuminOre Inc. (EPA Co. # 88450)	OWN	
870.1300	Acute Inhalation Toxicity	49565804	LuminOre Inc. (EPA Co. # 88450)	OWN	
870.2400	Primary Eye Irritation	49565804	LuminOre Inc. (EPA Co. # 88450)	OWN	
870.2500	Primary Dermal Irritation	49565804	LuminOre Inc. (EPA Co. # 88450)	OWN	
870.2600	Skin Sensitization	49565804	LuminOre Inc. (EPA Co. # 88450)	OWN	
870.3100	90-Day Oral Toxicity (rat)	00058020 & 00075116	Applied Biochemists (EPA Co. #8959) Kennecott Copper (EPA Co. # 44214)	OLD OLD	
870.3200	21-Day Dermal Toxicity	44127507	Griffin (EPA Co. # 1812)	OLD	
870.3700	Developmental Toxicity Study	44127506	Griffin (EPA Co. # 1812)	OLD	

Signature

Name and Title: **Eliot Harrison, Agent for LuminOre Inc.**

Date
February 11, 2015



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DATA MATRIX

Date February 11, 2015		EPA Reg. No./File Symbol 88450-		Page 3 of 5	
Applicant's/Registrant's Name & Address: LuminOre Incorporated, 6060 Corte del Cedro, Carlsbad, CA 92011		Product LuminOre CopperTouch Antimicrobial Copper Alloy Surfaces			
Ingredient(s): Elemental Copper (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5100	Reverse Mutation Assay	00085218	Dow Chemical (EPA Co. # 464)	OLD	
TOXICOLOGY (cont.)					
870.7485	General Metabolism	00062085	McCall Chemical Co (EPA Co. # 37952)	OLD	
NON-TARGET ORGANISM					
850.2100	Acute Avian Oral	00067456 00106120	Boliden Intertrade (EPA Co. # 1109) Boliden Intertrade (EPA Co. # 1109)	OLD	
850.1010	Aquatic Freshwater Invertebrate Toxicity (<i>daphnia magna</i>)	Cite-all	See attached list of data submitters	PAY	
850.1075	Acute Freshwater Fish toxicity (bluegill sunfish and rainbow trout)	Cite-all	See attached list of data submitters	PAY	
850.5400	Aquatic Plant Growth	43363601 43363602 43363603 43363604 43363605	Copper Sulfate Task Force (EPA Co. # 56501)	OLD OLD OLD OLD OLD	
ENVIRONMENTAL FATE					
835.2120	Hydrolysis	Not applicable			Footnote 14
835.2240	Photodegradation in Water	Not applicable			Footnote 14
850.6800	Activated Sludge Respiration Inhibition Test	Cite-All	See attached list of data submitters	PAY	
EFFICACY					
810.2300	Summary of Efficacy Studies Conducted with LuminOre Copper Touch Antimicrobial Copper Alloy Surfaces	49565805	LuminOre Inc. (EPA Co. # 88450)	OWN	Volume 5
Not Applicable	Characterization Assays of LuminOre CopperTouch Antimicrobial Copper/Nickel	49565806	LuminOre Inc. (EPA Co. # 88450)	OWN	Volume 6

Signature

Name and Title: **Eliot Harrison, Agent for LuminOre Inc.**

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DATA MATRIX

Date February 11, 2015	EPA Reg. No./File Symbol 88450-	Page 4 of 5
Applicant's/Registrant's Name & Address: LuminOre Incorporated, 6060 Corte del Cedro, Carlsbad, CA 92011	Product LuminOre CopperTouch Antimicrobial Copper Alloy Surfaces	

Ingredient(s): Elemental Copper (PC Code 22501)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.2300	Efficacy Evaluation of Copper Enhanced Hard Surfaces as a Sanitizer (<i>Staphylococcus aureus</i> & <i>Enterobacter aerogenes</i>). Study Number 872-102.	49565807	LuminOre Inc. (EPA Co. # 88450)	OWN	Volume 7
810.2300	Efficacy Evaluation of Copper Enhanced Hard Surfaces as a Sanitizer – Supplemental (<i>Pseudomonas aeruginosa</i> , Methicillin Resistant <i>Staphylococcus aureus</i> and <i>Escherichia coli</i> 0157:H7). Study Number 872-104.	49565808	LuminOre Inc. (EPA Co. # 88450)	OWN	Volume 8
810.2300	Efficacy Evaluation of Continuous Bacterial Contamination Reduction on Enhanced Hard Surfaces as a Sanitizer (<i>Staphylococcus aureus</i> & <i>Enterobacter aerogenes</i>). Study Number 872-106.	49565809	LuminOre Inc. (EPA Co. # 88450)	OWN	Volume 9
810.2300	Efficacy Evaluation of Continuous Bacterial Contamination Reduction on Enhanced Hard Surfaces as a Sanitizer – Supplemental (<i>Pseudomonas aeruginosa</i> , Methicillin Resistant <i>Staphylococcus aureus</i> and <i>Escherichia coli</i> 0157:H7). Study Number 872-110	49565810	LuminOre Inc. (EPA Co. # 88450)	OWN	Volume 10
810.2300	Efficacy Evaluation of Residual Self-Sanitizing Activity of Copper Enhanced Hard Surfaces (<i>Staphylococcus aureus</i> & <i>Enterobacter aerogenes</i>). Study Number 872-108.	49565811	LuminOre Inc. (EPA Co. # 88450)	OWN	Volume 11
810.2300	Efficacy Evaluation of Residual Self-	49565812	LuminOre Inc. (EPA Co. # 88450)	OWN	Volume 12

Signature

Name and Title: Eliot Harrison, Agent for LuminOre Inc.

Date
February 11, 2015



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DATA MATRIX

Date February 11, 2015		EPA Reg. No./File Symbol 88450-		Page 5 of 5	
Applicant's/Registrant's Name & Address: LuminOre Incorporated, 6060 Corte del Cedro, Carlsbad, CA 92011		Product LuminOre CopperTouch Antimicrobial Copper Alloy Surfaces			
Ingredient(s): Elemental Copper (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Sanitizing Activity of Copper Enhanced Hard Surfaces -Supplemental (<i>Pseudomonas aeruginosa</i> , Methicillin Resistant <i>Staphylococcus aureus</i> and <i>Escherichia coli</i> 0157:H7). Study Number 872-112.				

FOOTNOTES:

1. It is well established in the published literature that metallic copper is a reducing agent.
2. The flammability data requirement is not applicable since LuminOre CopperTouch Antimicrobial Copper Alloy Surfaces does not contain combustible liquids.
3. The explosability data requirement is not applicable since LuminOre CopperTouch Antimicrobial Copper Alloy Surfaces is not potentially explosive.
4. The storage stability/corrosion characteristics study will be submitted upon completion.
5. The miscibility data requirement is not applicable since LuminOre CopperTouch Antimicrobial Copper Alloy Surfaces is not diluted with petroleum solvents.
6. The dielectric breakdown voltage data requirement is not applicable since LuminOre CopperTouch Antimicrobial Copper Alloy Surfaces is not a liquid used around electrical equipment.
7. The pH data requirement is not applicable since neither metallic copper or LuminOre CopperTouch Antimicrobial Copper Alloy Surfaces is soluble or dispersable in water.
8. The viscosity data requirement is not applicable since LuminOre Copper Touch Antimicrobial Copper Alloy Surfaces is not a liquid.
9. The boiling point data requirement is not applicable since metallic copper is a solid at ambient temperature.
10. The dissociation constant data requirement is not applicable since metallic copper does not have any dissociable groups.
11. The partition coefficient data requirement is not applicable since metallic copper is not a non-polar organic substance.
12. The vapor pressure data requirement is not applicable since copper is non-volatile.
13. The basis for the acute toxicology study waivers are presented in Volume 4 of this submission.
14. According to the *Registration Eligibility Decision* (RED) document for the Coppers, these data requirements are not applicable.

Signature

Name and Title: Eliot Harrison, Agent for LuminOre Inc.

Date
February 11, 2015



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Ave, N.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date February 11, 2015	EPA Reg. No./File Symbol 88450-	Page 1 of 5
Applicant's/Registrant's Name & Address: LuminOre Incorporated, 6060 Corte del Cedro, Carlsbad, CA 92011	Product LuminOre CopperTouch Antimicrobial Copper Alloy Surfaces	

Ingredient(s): Elemental Copper (PC Code 22501)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			LuminOre Inc. (EPA Co. # 88450)	OWN	
			LuminOre Inc. (EPA Co. # 88450)	OWN	
			LuminOre Inc. (EPA Co. # 88450)	OWN	
			LuminOre Inc. (EPA Co. # 88450)	OWN	
			LuminOre Inc. (EPA Co. # 88450)	OWN	
			LuminOre Inc. (EPA Co. # 88450)	OWN	
			LuminOre Inc. (EPA Co. # 88450)	OWN	
			LuminOre Inc. (EPA Co. # 88450)	OWN	
			LuminOre Inc. (EPA Co. # 88450)	OWN	

			LuminOre Inc. (EPA Co. # 88450)	PL	

Signature 	Name and Title: Eliot Harrison, Agent for LuminOre Inc.	Date February 11, 2015
--	--	----------------------------------



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Ave, N.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date February 11, 2015		EPA Reg. No./File Symbol 88450-		Page 2 of 5	
Applicant's/Registrant's Name & Address: LuminOre Incorporated, 6060 Corte del Cedro, Carlsbad, CA 92011		Product LuminOre CopperTouch Antimicrobial Copper Alloy Surfaces			
Ingredient(s): Elemental Copper (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			LuminOre Inc. (EPA Co. # 88450)	PL	

			LuminOre Inc. (EPA Co. # 88450)	PL	

			LuminOre Inc. (EPA Co. # 88450)	OWN	
			LuminOre Inc. (EPA Co. # 88450)	OWN	

			LuminOre Inc. (EPA Co. # 88450)	PL	

			LuminOre Inc. (EPA Co. # 88450)	OWN	
			LuminOre Inc. (EPA Co. # 88450)	OWN	
			LuminOre Inc. (EPA Co. # 88450)	OWN	
			LuminOre Inc. (EPA Co. # 88450)	OWN	
			LuminOre Inc. (EPA Co. # 88450)	OWN	
			Applied Biochemists (EPA Co. #8959)	OLD	
			Kennecott Copper (EPA Co. # 44214)	OLD	
			Griffin (EPA Co. # 1812)	OLD	
			Griffin (EPA Co. # 1812)	OLD	

Signature

Name and Title: **Elliot Harrison, Agent for LuminOre Inc.**

Date
February 11, 2015



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Ave, N.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date February 11, 2015		EPA Reg. No./File Symbol 88450-		Page 3 of 5	
Applicant's/Registrant's Name & Address: LuminOre Incorporated, 6060 Corte del Cedro, Carlsbad, CA 92011		Product LuminOre CopperTouch Antimicrobial Copper Alloy Surfaces			
Ingredient(s): Elemental Copper (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Dow Chemical (EPA Co. # 464)	OLD	
			McCall Chemical Co (EPA Co. # 37952)	OLD	
			Boliden Intertrade (EPA Co. # 1109)	OLD	
			Boliden Intertrade (EPA Co. # 1109)	OLD	
			See attached list of data submitters	PAY	
			See attached list of data submitters	PAY	
			Copper Sulfate Task Force (EPA Co. # 56501)	OLD OLD OLD OLD OLD	
			See attached list of data submitters	PAY	
			LuminOre Inc. (EPA Co. # 88450)		
			LuminOre Inc. (EPA Co. # 88450)		

Signature 	Name and Title: Eliot Harrison, Agent for LuminOre Inc.	Date February 11, 2015
--	--	----------------------------------



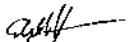
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Ave, N.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date February 11, 2015		EPA Reg. No./File Symbol 88450-		Page 4 of 5	
Applicant's/Registrant's Name & Address: LuminOre Incorporated, 6060 Corte del Cedro, Carlsbad, CA 92011		Product LuminOre CopperTouch Antimicrobial Copper Alloy Surfaces			
Ingredient(s): Elemental Copper (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			LuminOre Inc. (EPA Co. # 88450)		
			LuminOre Inc. (EPA Co. # 88450)		
			LuminOre Inc. (EPA Co. # 88450)		
			LuminOre Inc. (EPA Co. # 88450)		
			LuminOre Inc. (EPA Co. # 88450)		
			LuminOre Inc. (EPA Co. # 88450)		

Signature 	Name and Title: Eliot Harrison, Agent for LuminOre Inc.	Date February 11, 2015
--	--	----------------------------------



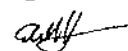
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Ave, N.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date	February 11, 2015	EPA Reg. No./File Symbol	88450-	Page 5 of 5	
Applicant's/Registrant's Name & Address: LuminOre Incorporated, 6060 Corte del Cedro, Carlsbad, CA 92011		Product LuminOre CopperTouch Antimicrobial Copper Alloy Surfaces			
Ingredient(s): Elemental Copper (PC Code 22501)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

Signature 	Name and Title: Eliot Harrison, Agent for LuminOre Inc.	Date February 11, 2015
--	---	---------------------------

CHEMICAL CHEMICAL NAME

022501 Copper as elemental

Company # Company Address

352 E. I. DU PONT DE NEMOURS AND COMPANY (MANAGER, REGISTRATION & REGULATORY AFF
1007 MARKET STREET
WILMINGTON, DE 19898

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y					Y	Y			Y

Company # Company Address

1266 MALTER INTERNATIONAL CORPORATION
P.O. Box 6099

NEW ORLEANS, LA 70174

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y									

Company # Company Address

2693 INTERNATIONAL PAINT LLC
2270 MORRIS AVE
UNION, NJ 07083

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y	Y		Y

Company # Company Address

2935 WILBUR-ELLIS COMPANY
2903 S. CEDAR AVENUE
FRESNO, CA 93725

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

3008 KOPPERS PERFORMANCE CHEMICALS, INC.
STEPTOE & JOHNSON LLP
1330 CONNECTICUT AVE., NW
WASHINGTON, DC 20036

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
					Y				

Company # Company Address

5185 BIO-LAB, INC.
P.O. Box 300002

LAWRENCEVILLE, GA 30049

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y									Y

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC

Pesticide Data Submitters List

By Active Chemical Code -Jan 5, 2015 Edition

Company # Company Address
7364 GLB POOL & SPA
(AN ARCH CHEMICALS, INC. BUSINESS)
90 BOROLINE ROAD
ALLENDAL, NJ 07401

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y				Y	Y	Y			

Company # Company Address
8959 APPLIED BIOCHEMISTS
(AN ARCH CHEMICALS, INC. BUSINESS)
90 BOROLINE ROAD
ALLENDAL, NJ 07401

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y					Y				Y

Company # Company Address
10465 CHEMICAL SPECIALTIES INC
C/O: VIANCE LLC.
200 EAST WOODLAWN ROAD, SUITE 350
CHARLOTTE, NC 28217

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y					Y				Y

Company # Company Address
20004 TRAYLOR CHEMICAL & SUPPLY CO.
P.O. Box 547937
1911 TRAYLOR BLVD.
ORLANDO, FL 32804

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
									Y

Company # Company Address
35896 PHIBRO-TECH, INC.
GLENPOINTE CENTER EAST, 3RD FLOOR
2856 GIRARD DRIVE
SUMTER, SC 29150

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y				Y	Y	Y			Y

Company # Company Address
39492 DEVCO COATINGS CO
DIVISION OF GROW GROUP, INC
925 EUCLID AVENUE
CLEVELAND, OH 44115

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address
45168 EXTENSOR AB
INTERNATIONAL PAINT LLC
2270 MORRIS AVENUE
UNION, NJ 07083

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
							Y		Y

Company # Company Address
56501 COPPER SULFATE TASK FORCE
P.O. Box 5209
VALDOSTA, GA 31603

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
					Y				

Company # Company Address
60061 KOP-COAT, INC
436 SEVENTH AVENUE
PITTSBURGH, PA 15219

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y	Y		

Company # Company Address
60111 BARDYKE CHEMICALS LIMITED
AMSYN INC
1011 HIGH RIDGE ROAD
STAMFORD, CT 06905

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
							Y		Y

Pesticide Data Submitters List

By Active Chemical Code -Jan 5, 2015 Edition

Company # Company Address

61943 CHEM-A-CO INC
REGISTRATIONS BY DESIGN, INC.
P.O. Box 1019

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

62190 ARCH WOOD PROTECTION, INC.
360 INTERSTATE NORTH PARKWAY, SUITE 450
ATLANTA,GA 30339

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

63005 SCM METAL PRODUCTS, INC.
P.O. Box 12166
2601 WECK DRIVE
RESEARCH TRIANGLE PARK,NC 27709

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
							Y		

Company # Company Address

66607 SPRAY DRIFT TASK FORCE
MCKENNA, LONG & ALDRIDGE LLP
1900 K STREET, NW
WASHINGTON,DC 20006

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

67262 RECREATIONAL WATER PRODUCTS, INC.
D/B/A RECREATIONAL WATER PRODUCTS
P.O. Box 1449

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
									Y

Company # Company Address

68250 LIQUITECH, INC.
421 EISENHOWER LANE SOUTH
LOMBARD,IL 60148

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y							Y		Y

Company # Company Address

69681 ALLCHEM PERFORMANCE PRODUCTS, INC.
ALLCHEM PERFORMANCE PRODUCTS
6010 NW FIRST PLACE
GAINESVILLE,FL 32607

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
							Y		

Company # Company Address

71227 SINANEN ZEOMIC COMPANY, LTD
TECHNOLOGY SCIENCES GROUP, INC.
1150 18TH STREET, N.W., SUITE 1000
WASHINGTON,DC 20036

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
			Y			Y	Y		Y

Company # Company Address

71537 CLEAR SOURCE ONE, LLC
4540 BRIDGEVILLE COURT
HUDSONVILLE,MI 49426

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
									Y

Company # Company Address

73667 APYRON TECHNOLOGIES, INC.
3342 INTERNATIONAL PARK DRIVE
ATLANTA,GA 30316

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Pesticide Data Submitters List

By Active Chemical Code -Jan 5, 2015 Edition

Company # Company Address

73989 FIFRA ENDANGERED SPECIES TASK FORCE, L
C/O HAROLD HIMMELMAN (BEVERIDGE & DIAM
1350 I STREET, NW
WASHINGTON, DC 20005

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

74888 RESIDENTIAL EXPOSURE JOINT VENTURE (RE
CSPA/PIR
1667 K STREET, NW, SUITE 300
WASHINGTON, DC 20006

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

75506 ARCH TREATMENT TECHNOLOGIES, INC.
360 INTERSTATE NORTH PARKWAY, SUITE 450
ATLANTA, GA 30339

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y	Y		Y

Company # Company Address

82012 COPPER DEVELOPMENT ASSOCIATION (CDA)
KELLEY DRYE & WARREN LLP
3050 K STREET, N.W., SUITE 400
WASHINGTON, DC 20007

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y						Y	Y		Y

Company # Company Address

82415 FUJI CHEMICAL INDUSTRIES, LTD.
ALTE BUILDING HIGOBASHI
1150 18TH STREET, N.W., SUITE 1000
WASHINGTON, DC 20036

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
							Y		

Company # Company Address

82874 LUMINORE INDUSTRIAL AND MARINE COATING
4350 TRANSPORT DRIVE, SUITE 110
VENTURA, CA 93003

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
									Y

Company # Company Address

83162 AMERICAN CHEMISTRY COUNCIL
ANTIMICROBIAL EXPOSURE ASSESSMENT TASK
700 2ND STREET, NE
WASHINGTON, DC 20002

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
	Y								

Company # Company Address

83498 ECOSMARTE PLANET FRIENDLY, INC.
1600 EAST 78TH STREET
RICHFIELD, MN 55423

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y									Y

Company # Company Address

85005 QUARTEK CORPORATION
KELLER & HECKMAN LLP
1001 G STREET, N.W., SUITE 500 WEST
WASHINGTON, DC 20001

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
					Y		Y		Y

Company # Company Address

85396 COPPERCOAT USA LLC
AG-CHEM CONSULTING LLC
12208 QUINQUE LANE
CLIFTON, VA 20124

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
							Y		

Pesticide Data Submitters List

By Active Chemical Code -Jan 5, 2015 Edition

Company # Company Address
85688 RAIN BIRD CORPORATION
STEELE PLANT - EXTRUSION OPERATIONS
1105 STEELE STATION ROAD
STEELE,AL 35987

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
					Y	Y	Y		Y

Company # Company Address
86131 ENRICH PRODUCTS, INC.
TECHNOLOGY SCIENCES GROUP, INC.
1150 18TH STREET, NW, SUITE 1000
WASHINGTON,DC 20036

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y						Y	Y		Y

Company # Company Address
88165 SCIESSENT LLC
TECHNOLOGY SCIENCES GROUP, INC.
1150 18TH ST., N.W., SUITE 1000
WASHINGTON,DC 20036

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
							Y		

Company # Company Address
88484 OCEOPROTEC SAS
KRK CONSULTING, LLC
5807 CHURCHILL WAY
MEDINA,OH 44256

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
									Y

Company # Company Address
88485 ENVIRONMENTAL WATER SOLUTIONS
KRK CONSULTING, LLC
5807 CHURCHILL WAY
MEDINA,OH 44256

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
							Y		Y

Company # Company Address
88539 AMERICAN CHEMISTRY COUNCIL
COPPER TASK FORCE
700 2ND STREET, NE
WASHINGTON,DC 20002

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
	Y			Y	Y				

Company # Company Address
88751 TOTO USA INC
TECHNOLOGY SCIENCES GROUP INC
1150 18TH STREET, N.W. SUITE 1000
WASHINGTON,DC 20036

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
							Y		Y

CHEMICAL CHEMICAL NAME

022501 Copper as elemental

Company # Company Address

352 E. I. DU PONT DE NEMOURS AND COMPANY (MANAGER, REGISTRATION & REGULATORY AFF
1007 MARKET STREET
WILMINGTON, DE 19898

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y					Y	Y			Y

Company # Company Address

1266 MALTER INTERNATIONAL CORPORATION
P.O. Box 6099

NEW ORLEANS, LA 70174

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y									

Company # Company Address

2693 INTERNATIONAL PAINT LLC
2270 MORRIS AVE
UNION, NJ 07083

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y	Y		Y

Company # Company Address

2935 WILBUR-ELLIS COMPANY
2903 S. CEDAR AVENUE
FRESNO, CA 93725

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

3008 KOPPERS PERFORMANCE CHEMICALS, INC.
STEPTOE & JOHNSON LLP
1330 CONNECTICUT AVE., NW
WASHINGTON, DC 20036

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
					Y				

Company # Company Address

5185 BIO-LAB, INC.
P.O. Box 300002

LAWRENCEVILLE, GA 30049

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y									Y

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC

e-Submission

Pesticide Data Submitters List

By Active Chemical Code -Jan 5, 2015 Edition

Company # Company Address

7364 GLB POOL & SPA
(AN ARCH CHEMICALS, INC. BUSINESS)
90 BOROLINE ROAD
ALLENTOWN, NJ 07401

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y				Y	Y	Y			

Company # Company Address

8959 APPLIED BIOCHEMISTS
(AN ARCH CHEMICALS, INC. BUSINESS)
90 BOROLINE ROAD
ALLENTOWN, NJ 07401

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y					Y				Y

Company # Company Address

10465 CHEMICAL SPECIALTIES INC
C/O: VIANCE LLC.
200 EAST WOODLAWN ROAD, SUITE 350
CHARLOTTE, NC 28217

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y					Y				Y

Company # Company Address

20004 TRAYLOR CHEMICAL & SUPPLY CO.
P.O. Box 547937
1911 TRAYLOR BLVD.
ORLANDO, FL 32804

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
									Y

Company # Company Address

35896 PHIBRO-TECH, INC.
GLENPOINTE CENTER EAST, 3RD FLOOR
2856 GIRARD DRIVE
SUMTER, SC 29150

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y				Y	Y	Y			Y

Company # Company Address

39492 DEVCO COATINGS CO
DIVISION OF GROW GROUP, INC
925 EUCLID AVENUE
CLEVELAND, OH 44115

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

45168 EXTENSOR AB
INTERNATIONAL PAINT LLC
2270 MORRIS AVENUE
UNION, NJ 07083

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
							Y		Y

Company # Company Address

56501 COPPER SULFATE TASK FORCE
P.O. Box 5209
VALDOSTA, GA 31603

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
					Y				

Company # Company Address

60061 KOP-COAT, INC
436 SEVENTH AVENUE
PITTSBURGH, PA 15219

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y	Y		

Company # Company Address

60111 BARDYKE CHEMICALS LIMITED
AMSYN INC
1011 HIGH RIDGE ROAD
STAMFORD, CT 06905

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
							Y		Y

Pesticide Data Submitters List

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Company # Company Address

61943 CHEM-A-CO INC
REGISTRATIONS BY DESIGN, INC.
P.O. Box 1019

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

62190 ARCH WOOD PROTECTION, INC.
360 INTERSTATE NORTH PARKWAY, SUITE 450
ATLANTA, GA 30339

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

63005 SCM METAL PRODUCTS, INC.
P.O. Box 12166
2601 WECK DRIVE
RESEARCH TRIANGLE PARK, NC 27709

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
							Y		

Company # Company Address

66607 SPRAY DRIFT TASK FORCE
MCKENNA, LONG & ALDRIDGE LLP
1900 K STREET, NW
WASHINGTON, DC 20006

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address

67262 RECREATIONAL WATER PRODUCTS, INC.
D/B/A RECREATIONAL WATER PRODUCTS
P.O. Box 1449

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
									Y

Company # Company Address

68250 LIQUITECH, INC.
421 EISENHOWER LANE SOUTH
LOMBARD, IL 60148

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y							Y		Y

Company # Company Address

69681 ALLCHEM PERFORMANCE PRODUCTS, INC.
ALLCHEM PERFORMANCE PRODUCTS
6010 NW FIRST PLACE
GAINESVILLE, FL 32607

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
							Y		

Company # Company Address

71227 SINANEN ZEOMIC COMPANY, LTD
TECHNOLOGY SCIENCES GROUP, INC.
1150 18TH STREET, N.W., SUITE 1000
WASHINGTON, DC 20036

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
			Y			Y	Y		Y

Company # Company Address

71537 CLEAR SOURCE ONE, LLC
4540 BRIDGEVILLE COURT
HUDSONVILLE, MI 49426

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
									Y

Company # Company Address

73667 APYRON TECHNOLOGIES, INC.
3342 INTERNATIONAL PARK DRIVE
ATLANTA, GA 30316

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Pesticide Data Submitters List

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Company # Company Address
73989 FIFRA ENDANGERED SPECIES TASK FORCE, L
C/O HAROLD HIMMELMAN (BEVERIDGE & DIAM
1350 I STREET, NW
WASHINGTON, DC 20005

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address
74888 RESIDENTIAL EXPOSURE JOINT VENTURE (RE
CSPA/PIR
1667 K STREET, NW, SUITE 300
WASHINGTON, DC 20006

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y			

Company # Company Address
75506 ARCH TREATMENT TECHNOLOGIES, INC.
360 INTERSTATE NORTH PARKWAY, SUITE 450
ATLANTA, GA 30339

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
						Y	Y		Y

Company # Company Address
82012 COPPER DEVELOPMENT ASSOCIATION (CDA)
KELLEY DRYE & WARREN LLP
3050 K STREET, N.W., SUITE 400
WASHINGTON, DC 20007

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y						Y	Y		Y

Company # Company Address
82415 FUJI CHEMICAL INDUSTRIES, LTD.
ALTE BUILDING HIGOBASHI
1150 18TH STREET, N.W., SUITE 1000
WASHINGTON, DC 20036

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
							Y		

Company # Company Address
82874 LUMINORE INDUSTRIAL AND MARINE COATING
4350 TRANSPORT DRIVE, SUITE 110
VENTURA, CA 93003

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
									Y

Company # Company Address
83162 AMERICAN CHEMISTRY COUNCIL
ANTIMICROBIAL EXPOSURE ASSESSMENT TASK
700 2ND STREET, NE
WASHINGTON, DC 20002

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
	Y								

Company # Company Address
83498 ECOSMARTE PLANET FRIENDLY, INC.
1600 EAST 78TH STREET
RICHFIELD, MN 55423

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y									Y

Company # Company Address
85005 QUARTEK CORPORATION
KELLER & HECKMAN LLP
1001 G STREET, N.W., SUITE 500 WEST
WASHINGTON, DC 20001

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
					Y		Y		Y

Company # Company Address
85396 COPPERCOAT USA LLC
AG-CHEM CONSULTING LLC
12208 QUINQUE LANE
CLIFTON, VA 20124

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
							Y		

Pesticide Data Submitters List

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Company # Company Address
 85688 RAIN BIRD CORPORATION
 STEELE PLANT - EXTRUSION OPERATIONS
 1105 STEELE STATION ROAD
 STEELE,AL 35987

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
					Y	Y	Y		Y

Company # Company Address
 86131 ENRICH PRODUCTS, INC.
 TECHNOLOGY SCIENCES GROUP, INC.
 1150 18TH STREET, NW, SUITE 1000
 WASHINGTON,DC 20036

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
Y						Y	Y		Y

Company # Company Address
 88165 SCIESSENT LLC
 TECHNOLOGY SCIENCES GROUP, INC.
 1150 18TH ST., N.W., SUITE 1000
 WASHINGTON,DC 20036

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
							Y		

Company # Company Address
 88484 OCEOPROTEC SAS
 KRK CONSULTING, LLC
 5807 CHURCHILL WAY
 MEDINA,OH 44256

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
									Y

Company # Company Address
 88485 ENVIRONMENTAL WATER SOLUTIONS
 KRK CONSULTING, LLC
 5807 CHURCHILL WAY
 MEDINA,OH 44256

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
							Y		Y

Company # Company Address
 88539 AMERICAN CHEMISTRY COUNCIL
 COPPER TASK FORCE
 700 2ND STREET, NE
 WASHINGTON,DC 20002

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
	Y			Y	Y				

Company # Company Address
 88751 TOTO USA INC
 TECHNOLOGY SCIENCES GROUP INC
 1150 18TH STREET, N.W. SUITE 1000
 WASHINGTON,DC 20036

Data Types									
EFF	EXP	EXU	FA	FEP	FRE	OT	PC	RC	TC
							Y		Y

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W. Suite 505
Washington, DC 20001

telephone 202.393.3903
fax 202.393.3906

February 10, 2015

Seiichi Murasaki, Acting Product Manager (33)
Regulatory Management Branch #1
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: Product: LuminOre CopperTouch Antimicrobial Surfaces
EPA File Symbol No. 88450-
Active Ingredient: Copper
Registrant: LuminOre Incorporated
Registration Application for New End-Use Product
PRIA Code A540
Electronic Submission

Dear Mr. Murasaki:

On behalf of LuminOre Incorporated, I am submitting a registration application for LuminOre Copper Touch Antimicrobial Surfaces, a new end-use product. The product, as distributed, is a copper coated substrate that provides continuous antimicrobial (sanitizer) activity. The substrates that will be part of LuminOre CopperTouch Antimicrobial Surfaces are metals, plastics, and wood/wood composites. Please note that LuminOre CopperTouch Antimicrobial Surfaces is substantially similar to the copper products registered by the Copper Development Association (CDA), e.g. Antimicrobial Copper Alloys –Group I, Reg. No. 82012-1. The only difference between the products is that LuminOre CopperTouch Antimicrobial Surfaces comprises copper, a binding agent and a substrate while the CDA products are just a copper alloy. The uses and label claims for both products are identical.

LuminOre had several meetings with Antimicrobials Division (AD) staff prior to the submission of this application. The pertinent correspondence from those meetings is attached.

e-Submission

In support of this application, please find enclosed the following documents:

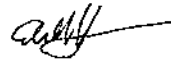
- Application for Pesticide Form.
- Confidential Statement of Formula (CSF) Form.
- Certification with Respect to Citation of Data Form.
- Transmittal Document.
- Data Matrix (Agency and Public Copies).
- Proposed Product Label.
- Product Chemistry and Efficacy Data (3 copies).
- Waiver Requests for Acute Toxicology Data.

LuminOre is relying on the "select method" to support this registration application. Therefore, the enclosed data matrix identifies all the studies applicable to the subject registration applications and notes how LuminOre intends to fulfill each data requirement. The applicable data requirements are taken from the *Reregistration Eligibility Decision* (RED) document for Coppers and the Part 158 data requirements from antimicrobials.

The PRIA Category for this registration action is A540. A copy of the PRIA payment is attached. Please note that LuminOre Inc eligible for a 75% PRIA fee waiver reduction. Substantiation that LuminOre Inc. qualifies for this reduction is attached.

If you have any questions about this submission or need additional information, please contact me at (202) 393-3903, ext. 14 or by e-mail at eharrison@lewisharrison.com.

Sincerely,



Eliot Harrison
Agent for LuminOre Inc.

